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U.S. ENVIRONMENTAL PROTECTION AGENCY
PRESENTATION OF THE APPROACH
TO REEVALUATE ATRAZINE

U.S. EPA
One Potomac Yard, South Building
2777 South Crystal Drive
Arlington, Virginia 22202

NOVEMBER 3, 2009

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PRESENTATION OF THE APPROACH
TO REEVALUATE ATRAZINE
OPEN MEETING

November 3, 2009

MR. BAILEY: Good morning, everyone. My name is Joe Bailey, and I'll be serving as the Designated Federal Official for this FIFRA Scientific Advisory Panel meeting.

The topic for this meeting is presentation of the approach to reevaluate atrazine. I might add that this is an informational meeting to present the plan for reevaluation in 2010.

As the Designated Federal Official, I serve as a liaison between the Agency and the public and the panel to ensure that all FACA requirements are met.

Dr. Heeringa, sitting next to me, will be serving as the chair for this meeting, and the panel only provides independent, scientific peer review and advice...and advice to the Agency on pesticide issues. The panel only provides advice and recommendations, and EPA does all the regulatory and decision making and implementation authority associated with pesticide issues.



1 This meeting does provide an opportunity
2 for public comment. I think it's projected to begin
3 about 9:30 this morning. I have a number of people who
4 have requested to make comments ahead of time, and if
5 there's anyone else in the audience that wishes to make
6 public comments, please let me or anybody else on the
7 SAP staff here know, and if you do walk up and request
8 to comment this morning, we'll have to limit your time
9 to five minutes or...or fewer.

10 We have a public docket associated with
11 the meeting as well. A number of comments have been
12 submitted to that. It is accessible to the public,
13 and...and the presentations and any other material that
14 is brought forward during this meeting will be placed
15 in that docket and available to the public within a few
16 days as well.

17 After the meeting is over, we will
18 prepare a meeting minutes or report, and that also will
19 be available on the web site and...and in the public
20 docket.

21 And I think at this point, I will turn
22 the meeting to the chair, Dr. Heeringa.

23 **DR. HEERINGA:** Thank you very much, Joe.
24 And as Joe mentioned, I'd like to welc...welcome all of
25 you to this administrative meeting of the FIFRA Science



1 Advisory Panel with the subject and a briefing on the
2 presentation of the approach to reevaluate atrazine.

3 Before we begin, I'd like to have the
4 members of the permanent FIFRA Science Advisory Panel
5 introduce themselves and begin with Dan Schlenk.

6 **DR. SCHLENK:** Good morning. My name is
7 Dan Schlenk. I'm a professor of aquatic ecotoxicology
8 at the University of California at Riverside in the
9 Department of Environmental Sciences. My areas of
10 expertise are primarily mechanisms of action, merging
11 contaminants, and pesticides in aquatic organisms.

12 **DR. HEERINGA:** And I am Steve Heeringa,
13 the chair, currently, of the FIFRA Science Advisory
14 Panel. I'm a research scientist and professor at the
15 University of Michigan. I'm an applied statistician by
16 training.

17 **DR. POPE:** Good morning. I'm Cary Pope.
18 I'm a professor of toxicology at Oklahoma State
19 University Center for Veterinary Health Sciences. I'm
20 a neurotoxicologist, and my primary interest is in
21 toxicity of pesticides.

22 **DR. PORTIER:** Good morning. I'm Ken
23 Portier, Director of Statistics at the American Cancer
24 Society national home office in Atlanta. I'm an
25 applied biostatistician with 30 years of experience in



1 agriculture and public health.

2 **DR. CHAMBERS:** I'm Jan Chambers. I'm a
3 professor at the College of Veterinary Medicine at
4 Mississippi State University. I'm a pesticide
5 toxicologist with emphasis on neurotoxicology and
6 metabolism.

7 **DR. BUCHER:** I'm John Bucher. I'm the
8 associate director of the National Toxicology Program
9 in Research Triangle Park at NIEHS. I have a general
10 interest in all kinds of issues related to toxicology
11 and...and carcinogenesis.

12 **DR. HEERINGA:** Thank you very much,
13 members of the panel, and I think at this point, with
14 those introductions, that we're ready to begin, and I'd
15 like to turn first to Steve Bradbury who is deputy
16 director of the Office of Pesticide Programs in the
17 EPA. Good morning, Steve.

18 **DR. BRADBURY:** Thank you, Dr. Heeringa,
19 and I'd like to welcome the panel to today's meeting
20 and also thank Joe Bailey and the staff of the Office
21 of Science Coordination and Policy for helping to
22 organize the meeting today.

23 I'd also like to introduce some of the
24 colleagues with me today before I just give a brief
25 little background to today's meeting. Dr. Tina Levine



1 will be speaking after...after I finish my comments as
2 the director of our Health...Health Effects Division.

3 Next to her is Don Brady who's the
4 director of our Environmental Fate and Effects
5 Division. Elaine Francis, Dr. Elaine Francis from
6 Office of Research and Development is the national
7 program director for ORD's pesticides and toxics
8 research. And Dr. Ed Ohanian, to my left, is the
9 director of the Health and Ecological Criteria Division
10 in the Office of Water.

11 As we'll be discussing briefly this
12 morning, the science review plan that will be
13 undertaken during 2010 includes close collaboration
14 with our colleagues in the Office of Research and
15 Development and the Office of Water, so I wanted to
16 make sure they were here with us today as...as we go
17 forward and outline what we'll be doing over the course
18 of the next year or so.

19 Tina...when...when Dr. Levine gives her
20 comments, she'll introduce the members of our team or
21 our team leaders who will be taking the point in...in
22 going through the...the peer review process over the
23 next year or so.

24 As Joe indicated, today's meeting is an
25 informational meeting. It's a meeting where we're...we



1 want to share with you in words to complement what's in
2 text with the paper that you all received about a month
3 ago which is describing the...the science review plan
4 over the course of the next year. So, the purpose of
5 today's meeting isn't to get into the scientific issues
6 associated with the upcoming peer review but to provide
7 some context to the peer review and discuss, broadly,
8 sort of the scope of each of the three peer reviews
9 that we'll be having during the course of the
10 coming...coming year.

11 What I'd like to do is just spend a few
12 minutes providing a little context on...on atrazine and
13 its regulatory history. We'll touch on some of the
14 previous Science Advisory Panel reviews that we've had,
15 and then I'll turn it...turn it over to Dr. Levine who
16 can go into a little bit more detail on the context
17 of...of the upcoming year.

18 Atrazine was first registered, actually,
19 by USDA back in 1958 as a herbicide, a broad spectrum
20 herbicide. It's used both at plant and post-plant,
21 and, currently, it's primarily used in corn, sorghum
22 production, sugarcane and, to some degree, in turf,
23 especially in the southeast.

24 In the early '80s, in 1983, EPA issued a
25 registration standard which was some of the early



1 phrases associated with the registration process and
2 the re-registration process, and at that time, the
3 Agency indicated that it wanted to keep track of the
4 potential of cancer, carcinogenicity of atrazine, and
5 also indicated the importance of groundwater and
6 surface water protection with the use of atrazine.

7 Throughout the 1990s, there were a
8 series of voluntary adjustments to the label or to the
9 use practices of atrazine, and these primarily focused
10 on risk reduction measures to ensure minimal exposure
11 to surface water and groundwater, particularly in the
12 context of drinking water sources.

13 And associated during the time frame of
14 the 1990s, there were rate reductions, setbacks from
15 wells, setbacks from stream banks and...and water
16 bodies. Also at that time, the compound received a
17 restricted use classification for just about all of its
18 uses, and in large part, that was involving the need to
19 try to keep the product from getting into the water due
20 to runoff.

21 In 1994, the Agency initiated a special
22 review for not only atrazine but the other triazine
23 herbicides, and the focus of that special review was
24 around the potential for atrazine to cause cancer as
25 well as the importance of minimizing exposure of



1 atrazine to groundwater and surface water.

2 As we move from the '90s into the early
3 2000s, there were two SAPs that were held, one in 2000
4 and one in 2003. Essentially, the outcome of those
5 Science Advisory Panel reviews was that atrazine was
6 not likely to be carcinogenic in humans, and so, the
7 concern about carcinogenicity was researched and
8 studied during the '80s, during the '90s, leading to
9 the SAP recommendations in 2000 and 2003 looking at
10 prostate cancer, but sort of reaching the conclusion
11 that it was not likely that atrazine was carcinogenic
12 in humans.

13 In January of...of 2003, the Agency
14 issued an IRED, an Interim Re-registration Eligibility
15 Decision which culminated much of the science that had
16 been developing over the last ten years. In that
17 decision, we re-registered the product and incorporated
18 some of the additional mitigations that I've described
19 before in terms of protecting groundwater and surface
20 water, also some additional protections for workers as
21 well. And at that time, we also...the Agency also
22 established a drinking water monitoring program to
23 ensure the concentrations of atrazine in drinking water
24 source waters as well as finished water did not reach
25 our levels of concern.



1 In October of 2003, we issued a revised
2 IRED or Interim Re-registration Eligibility Decision
3 which included a memorandum of agreement with the
4 registrants to sort of memorialize the monitoring
5 programs for drinking water. It also established a
6 monitoring program associated with ecological systems,
7 in particular, assessing whether or not atrazine was
8 reaching levels of concern in terms of protecting
9 aquatic communities. Also, that IRED in October of
10 2003 summarized where we were in terms of looking at
11 the potential effects of atrazine on amphibian gonadal
12 development as well.

13 In 2006, the Agency issued a triazine
14 cumulative risk assessment, and so, the atrazine
15 Interim Re-registration Eligibility Decision became a
16 Registration Eligibility Decision, because the
17 cumulative assessment had been completed for the
18 triazine herbicides.

19 Right now, atrazine is scheduled to
20 initiate registration review in...in 2013.

21 Now, through all this time frame of the
22 '80s and '90s into...into where we are today, as you
23 all know, if not directly at least from your
24 colleagues, your predecessors on the Science Advisory
25 Panel, we spent a lot of time going through a number of



1 issues with the Science Advisory Panel to help guide us
2 in...in interpreting the science and...and, ultimately,
3 to inform our decisions, and let me just do a quick
4 snapshot on some of those previous SAPs.

5 I mentioned the...the efforts to better
6 understand the potential of atrazine to cause cancer
7 and what some of its mechanisms and mode of action may
8 be. There were peer reviews in 1998 as well as 2000
9 that led us to the conclusion, with your advice and
10 counsel, that the neuroendocrine mechanisms of action
11 likely associated with atrazine with the cancer
12 observed in rodents is probably not...is likely not to
13 be operable in humans. However, the neuroendocrine
14 mode of action was an important mechanism for us to
15 focus on in terms of our risk assessment in human
16 health protection.

17 So, we went through that 2000 SAP, the
18 conclusion that atrazine's mechanism of action was
19 likely associated with the neuroendocrine mechanism of
20 action. The cancer observed in rodents probably was
21 not likely relevant in humans because of the
22 differences in the biological models but focusing on
23 that neuroendocrine mechanism of action as initiating
24 events as being the focus of...of the risk assessment
25 which was the focus, then, of that IRED in 2003.



1 In 2002, we also had a Science Advisory
2 Panel looking at the cancer issue in, for example,
3 prostate cancer, looking at a study in a manufacturing
4 plant where atrazine was manufactured to determine
5 whether or not there was an association between
6 prostate cancer and atrazine exposure. The conclusion
7 of that SAP in followup work was that it was not likely
8 that atrazine was associated with the prostate cancer
9 for the workers in that plant. However, the Agency
10 continues to monitor the literature in terms of
11 atrazine's potential cancer effects which I'll touch
12 upon in a little bit.

13 In addition to the...the reviews
14 regarding human health, we also through the 2000s met
15 with you four times to discuss atrazine's potential
16 role in terms of ecological effects and risk, and there
17 were two Science Advisory Panels discussing...exploring
18 the potential of atrazine to cause gonadal
19 developmental effects in amphibians.

20 In 2003, we had an SAP that looked at
21 literature that had been published at the time and
22 proposed that the literature established a strong
23 hypothesis that atrazine may be able to cause amphibian
24 gonadal development effects, and we proposed a research
25 or a study design to you to follow up on that



1 hypothesis, and we sort of worked through that.

2 And then, with your advice on that study
3 protocol, asked the registrant, required the registrant
4 to do that study protocol and then came back in 2007
5 with the results from that study as well as other
6 literature that had been published in the open
7 literature since that time and concluded from that peer
8 review that at least up to 100 ppb atrazine, we weren't
9 seeing effects on gonadal development. But again,
10 focusing on ongoing research as it gets published in
11 the literature since 2007.

12 We also spent some time, two SAPS, one
13 in 2007 and one just this last spring, looking at the
14 effects of atrazine on aquatic communities, in
15 particular, getting feedback on how to interpret
16 effects of atrazine on aquatic communities and how to
17 integrate that with the monitoring program to help
18 elucidate where there may be vulnerable watersheds in
19 terms of...of atrazine exposure.

20 Given sort of where we are in the state
21 of the science, our focus for 2010 is to focus on the
22 human health effects as our...as our area of emphasis
23 as we go into 2010, and we'll revisit some of the
24 ecological effects after we get through the...the human
25 health effect risk assessments.



1 So, what will be...if I could have the
2 next slide forwarded please...what our white paper
3 describes is a series of...of three peer reviews
4 over...over 2010. We'll just wait a second and see if
5 this slide will come up. There you go...so there will
6 be a series of three Science Advisory Panel meetings,
7 one in February 2010, one in April of 2010, and one in
8 September of 2010.

9 As we put forth our science...our review
10 plan, we wanted to take advantage of...of SAPs that we
11 already had scheduled. As you know, in February 2010,
12 we already had a Science Advisory Panel meeting
13 scheduled on the issue of how to incorporate
14 epidemiological studies with experimental studies and
15 how to develop those lines of evidence and integrate
16 those lines of evidence.

17 And what we've done is added a case
18 study to that February SAP which will look at some
19 recent epidemiological studies associated with atrazine
20 and get some advice not only on those studies but also,
21 more broadly, methodological insights into how to
22 integrate different kinds of epidemiological study
23 designs as well as, more broadly, how to integrate
24 epidemiological studies with experimental studies.

25 So, in a sense a building block as we



1 move throughout...through the year. That panel meeting
2 will also include some discussion around the
3 agricultural health study and how to take a look at
4 different ways of estimating exposure in different
5 kinds of epidemiological studies and how to integrate
6 some of that information.

7 In April 2010, we'll focus on
8 experimental studies, both in vitro and in vivo
9 studies, and review the previous risk assessment,
10 review any new information that's come out since that
11 time, and take a look at some of the critical aspects
12 of hazard identification, dose response relationships,
13 as Tina will describe in a bit more detail.

14 We'll also take a look at how our
15 toxicological interpretation influences sampling
16 designs in terms of monitoring drinking water sources
17 to ensure the frequency of sampling matches the
18 dosimetry that we're elucidating through the
19 toxicological studies.

20 So, that's a new review that wasn't
21 scheduled previously.

22 The September 2010 SAP, again, will
23 build on an SAP that was already scheduled. As I
24 mentioned before, we continue to look at the potential
25 of atrazine to cause cancer. As I said, we've



1 determined that atrazine is not likely a human
2 carcinogen.

3 However, we wanted to keep track of
4 epidemiological studies as they progress and,
5 particularly, the ag health study which has two or
6 three studies that we anticipate being published this
7 spring or summer which will be very important to take a
8 look at the cancer issue.

9 So, in 2010, we'll not only take a look
10 at the ag health study; we'll look at other epi studies
11 in terms of cancer, non-cancer, integrate that with the
12 animal or the experimental toxicology studies, and try
13 to bring it all together in September, 2010.

14 In closing, before I turn it over to
15 Tina, I just want to indicate that as we approach this
16 peer review process, we'll be taking advantage of
17 Agency guidance in terms of how we do risk assessments,
18 in terms of the NAS.

19 And the risk assessment paradigm, using
20 our risk characterization handbook in terms of ensuring
21 transparency and clarity, consistency, reasonableness
22 in how we interpret our assumptions and integrate the
23 data and also be taking a look at the National Academy
24 report on 21st century toxicology, the importance of
25 toxicity pathways, and how to interpret the information



1 that will be before us.

2 So, with that, unless there are any
3 clarifying questions, I'll turn it over to Dr. Levine
4 now.

5 **DR. HEERINGA:** Thank you, Dr. Bradbury.
6 Dr. Levine?

7 **DR. LEVINE:** Thank you. I would also
8 like to thank the panel for all the time and effort you
9 bring to bear on our risk assessments, and your input
10 is critical to ensuring that our risk assessments are
11 transparent and are based on strong science.

12 And I would like to introduce at least
13 the shell of the team. There's going to be a lot of
14 people in HED working on this over the next year. I
15 would like to introduce the...the leads for the
16 project. First, Dr. Anna Lowit who's to the left of
17 Steve Bradbury is going to be the overall lead for the
18 three SAPS, and she also has the lead on the February
19 meeting.

20 And next to her is Dr. Elizabeth Mendez
21 who is taking the lead for the April meeting that's
22 going to look at the laboratory data.

23 And to the left of Ed Ohanian is soon-
24 to-be Dr. Carol Christiansen who's finishing her Ph.D.
25 in epidemiology and is going to take the lead on the



1 September meeting.

2 So, this is going to be...these are
3 going to be our principal players, but there are going
4 to be a lot of people going through a lot of studies
5 and working through the issues.

6 And I...a lot of this I think Steve has
7 touched upon and I will be brief, but as Steve said, we
8 signed the...the atrazine RED in 2003, and we used the
9 best available science at the time to support the RED,
10 and we used well accepted and publicly vetted Agency
11 guidance in the way we approached it and also had three
12 SAPS on the human health side, the one in 1998 that
13 looked at the mammary gland tumors in rats, the one in
14 2000 that looked at the neuroendocrine mode of action,
15 and the 2003 SAP on epidemiology of prostate cancer.

16 We based our...our science on a mode of
17 action approach as the foundation for our dose response
18 and extrapolation from animals to humans and among
19 humans, and the 2000 SAP supported this approach, and,
20 basically, we believe that atrazine works via a
21 neuroendocrine mode of action which ultimately leads to
22 the various toxic effects that are seen in the animal
23 data.

24 And as our point of departure, we used
25 attenuation of the pre-ovulatory luteinizing hormone

1 surge as a biomarker of disruption of hypothalamic
2 function, and that's what we are basing...based our
3 risk assessments of various scenarios on.

4 In this year-long review, we'll be
5 looking at a thorough, objective review of new science
6 and integrating it into the existing science that we
7 based our 2003 RED on.

8 We'll be placing emphasis on evaluating
9 mode of action and action pathways to toxicity, because
10 we believe that understanding how a chemical works in
11 the body will help us better interpret dose response
12 data, life stage susceptibility, and the factors that
13 lead to susceptibility, and also that mode of action
14 provides a strong science for explicitly considering
15 human relevance, the relevance of animal data to...to
16 human health effects.

17 We'll be reconsidering all aspects of
18 the hazard assessment, specifically, the critical
19 effects used to extrapolate risk, the points of
20 departure used for the margin of exposure calculation
21 and the relevant durations of exposure, and, finally,
22 the...the life stage susceptibility and what impacts
23 the statutory requirement for the 10x factor to protect
24 infants and children unless we have strong science
25 that, data that allows us to change that..



1 And as Steve mentioned, we're doing this
2 through three SAPs, and so the rest of this talk is to
3 basically try to provide a little bit more detail on
4 the three SAPs.

5 Again, the February meeting has...has
6 always been on the schedule, and it really has a
7 broader purpose than just atrazine, but some of the
8 atrazine data fits very well into the broad purpose of
9 the February meeting.

10 We had planned to do this meeting for a
11 while, because especially with all of the data coming
12 out of the Ag Health Study which is a rather major
13 prospective study of 90,000 certified pesticide
14 applicators from North Carolina and Iowa, that's a
15 collaboration between NCI and NIHS and EPA, both the
16 pesticide program and the ORD scientists, we've been
17 getting information and we're getting regular updates
18 on various outcomes of the epidemiological prospective
19 study, and we realized that we needed to develop a
20 framework for incorporating this data...these data into
21 our risk assessments.

22 So, what we plan to do in February is
23 develop a white paper framework based upon...building
24 on the human relevancy framework that the Agency
25 already has, and...and that was a big part of what we



1 were planning to do in February, and we wanted to
2 basically vet this framework with some case studies.
3 And our framework is going to use, you know, weight of
4 evidence approach and best available information for
5 humans and animals, and will again, as I said,
6 emphasize mode of action and toxicity pathways, and
7 it's quite consistent with guidance that's already out
8 there that maybe doesn't specifically address a little
9 of the epidemiology data that may be coming down the
10 pike.

11 And we also wanted to take advantage
12 of...of increases of incident data. We've been beefing
13 up our ability to analyze the data that we have
14 from...from our 6A2 incident reporting and also from
15 poison control center data, and so, we wanted to use
16 this SAP to try and evaluate that, too.

17 So, we're going to have three case
18 studies, and the first case study will be the atrazine-
19 related case study, a review of several recent
20 epidemiology studies that have been fairly well
21 publicized and have come to our attention. And most of
22 these, I think, are in the category of
23 hypothesized...hypothesis generating, some, a lot of
24 them are ecologic, and we will be soliciting comments
25 from the panel on ways to consider these types of



1 studies in risk assessment.

2 And then, the second case study is going
3 to involve the Ag Health, but it's not...it's going to
4 be actually the exposure part of the Ag Health. We're
5 going to be...we're in the early stages of performing a
6 side by side comparison of the exposure assessment
7 approaches used in the Ag Health study to those that
8 OPP routinely uses. And the second component of the
9 exposure assessment case study involved evaluating co-
10 exposure to multiple pesticides.

11 The third case study will involve a
12 retrospective analysis of reported human incidents from
13 exposure to an organophosphate pesticide that
14 historically has been used in residential settings.

15 It's important for the panel and the
16 public to keep in mind that although the February SAP
17 will explicitly involve consideration of some atrazine
18 epidemiologic studies, there really is a broader intent
19 for this meeting.

20 The second SAP in 2010 is planned for
21 April and will focus on experimental laboratory
22 studies, from both in vitro and in vivo situations, and
23 we will discuss our preliminary considerations for the
24 updated hazard identification and dose response
25 characterization. And as I will discuss in a few



1 minutes, we will also be discussing...and, actually,
2 Steve mentioned it... that we'll also discuss some of
3 the drinking water monitoring issues.

4 We will be performing a comprehensive
5 literature review of studies related to human health
6 for atrazine. The April meeting will focus on our
7 preliminary evaluation of these studies.

8 As I noticed...I noted a few minutes
9 ago, we're going to emphasize mode of action as a
10 starting point for thinking about the dose response and
11 life stage susceptibility, and we will also consider
12 those studies used in the 2003 assessment as well as
13 more recent studies investigating a variety of
14 hypotheses. For example, we have identified new
15 studies on mammary gland development, neurotoxicity,
16 endocrine disruption, immunotoxicity, and studies on
17 atrazine metabolites that we will be considering.

18 In April, we will be soliciting comments
19 on our preliminary review of the updated critical
20 effects and our preliminary evaluation of dose
21 response. And one of the key areas of interest in the
22 new analysis will be evaluating life stage effects and
23 considering the factors that lead to life stage
24 susceptibility as we think about the science that
25 informs the FQPA 10x factor.



1 As Steve told you a few minutes ago, the
2 temporality of the critical effect is an important
3 aspect of this risk assessment. This is because
4 monitoring frequency for community water systems should
5 be related to toxic effects being used to develop the
6 human health risk assessment.

7 In light of this, we'll be putting a lot
8 of focus during our analysis on considering
9 developmental windows of susceptibility, time course of
10 toxicokinetic and toxicodynamic factors.

11 Drinking water exposure is the major
12 pathway by which people are exposed in the United
13 States to atrazine. Temporal window is relevant for
14 toxicity endpoints that inform the exposure assessment.
15 Specifically, in a case where acute effects are of
16 greatest concern, monitoring must be done more
17 frequently to ensure that the peaks are detected and
18 also if chronic effects, like cancer, are of greatest
19 concern, then monitoring can be done less frequently.

20 For the September meeting, the Agency
21 will solicit comments from the SAP on three areas,
22 epidemia out...epidemiological studies on cancer and
23 non-cancer effects, experimental studies/laboratory
24 studies on cancer and non-cancer effects, and pulling
25 it all together, the integrated weight of evidence,



1 hazard dose response and exposure assessment and
2 characterization.

3 The epidemiology studies, we expect to
4 have new studies from the Ag Health study. It's
5 expected, I think, in the spring, and there will be
6 other scientific reports, and there also will be the
7 epidemiology studies that we first raise in February,
8 in the February meeting next...that's coming up early
9 next year, and other scientific reports.

10 We will discuss a weight of evidence
11 approach in February which involves using the best
12 available science from humans and animals, and we plan
13 to apply this approach at the September meeting.
14 Specifically, we will integrate all of the information
15 in February and April along with additional
16 epidemiology studies and do a new hazard
17 characterization for atrazine.

18 In the event that new studies come out
19 between April and September from in vitro or in vivo
20 studies, we'll also include these. And at the
21 September meeting, we'll provide our proposals for
22 updated points of departure and FQPA safety factors.

23 We will also update our thoughts on
24 sampling frequency considerations based on the April
25 SAP and if there are any potential revisions in



1 sampling design options, or if any changes in the
2 atrazine risk assessment are proposed, those will be
3 discussed at the September meeting.

4 And in light of the new science and the
5 feedback we get from the panel, the Agency will
6 determine if the risk assessment for atrazine should be
7 revised and whether the drinking water monitoring
8 frequency requirements should be changed.

9 So, again, here is the summary slide
10 that Steve gave you at the end of his talk. At the
11 February meeting, we're incorporating the epidemiology
12 study and human health incident data and risk
13 assessment. We're also going to be doing some stuff
14 on...work on exposure assessments in epidemiology and
15 comparing them to other...other ways in which we assess
16 exposure, and we're going to do a case study using
17 recent atrazine hypothesis generating epidemiology
18 studies.

19 In April will be the preliminary
20 evaluation of in vitro and in vivo lab studies,
21 preliminary identification of critical effects and dose
22 response assessment and some discussion of the
23 frequency of atrazine monitoring in drinking water
24 sources.

25 And in September, we will focus on the



1 epidemiology studies for cancer and non-cancer,
2 integrate everything into a weight of evidence and
3 hazard characterization, and, again, revisit the
4 frequency of atrazine monitoring in drinking water
5 sources.

6 And with that, I thank the panel for
7 their time and attention.

8 **DR. HEERINGA:** Thank you very much, Dr.
9 Levine.

10 Just an opportunity for quick questions
11 of clarification from the...the panel members for
12 either Steve Bradbury or Tina Levine?

13 (No response.)

14 **DR. HEERINGA:** With that, I think we'll
15 have an opportunity after the period of public comment,
16 too. They will be here. Are we ready to move on then?

17 At this point in our meeting, then, I
18 believe we're ready to move on to the period of public
19 comment. I just want...

20 OFF THE RECORD

21 **(WHEREUPON,** there was a pause in the proceedings.)

22 **DR. HEERINGA:** Okay, let's return to the
23 proceedings of our meetings. For anyone who has joined
24 us through the teleconference line to...as a companion
25 to the webcast, welcome to this morning's informational



1 meeting of the FIFRA Science Advisory Panel on the
2 presentation of the approach to reevaluate atrazine.

3 We are at the point in the morning
4 meeting where we have an opportunity for public
5 comment, and we have eight parties that have registered
6 with Joe Bailey to present public comment, but before
7 we begin those, I would like to draw your attention
8 also to the docket for this meeting in which there
9 are...I won't try to count it but approximately eight
10 double-spaced pages of registered docket comments from
11 various parties who have submitted public comment,
12 written form public comment and supporting materials
13 for this meeting.

14 This morning, though, we're going to
15 hear from eight public commenters representing various
16 groups and various interests, and they will be called
17 up to present in order that they were registered with
18 Joe Bailey, and I'd like to begin with Scott Slaughter
19 of the Center for Regulatory Effectiveness. So, Scott,
20 are you here?

21 It could be possible to use any one of
22 these microphones on the side.

23 **MR. SLAUGHTER:** That works. I'm Scott
24 Slaughter, and I'm here commenting on behalf of the
25 Center for Regulatory Effectiveness. We have three



1 comments at this point.

2 First, any alleged endocrine effects
3 from atrazine should be reviewed and assessed by the
4 endocrine disruptor screening program, not these SAPs,
5 not any other process within EPA.

6 Second, these SAPs are not motivated by
7 science. They are politically motivated.

8 Third, the EPA political appointees need
9 to defend the SAPs and the EPA staff who've worked on
10 atrazine in the past from the personal attacks on their
11 competency that have been waged by various NGOs, blogs,
12 and media and individuals.

13 The first point is that any alleged
14 endocrine effects from atrazine should be reviewed and
15 assessed in EDSP, not in EPA's proposed SAPs and not in
16 some other context at EPA. EPA has already send out
17 EDSP test orders for atrazine.

18 EPA told the EDSP SAP that the EDSP
19 process would identify any endocrine effects by
20 pesticides, including atrazine. If so, then
21 additional review of endocrine effects by these SAPs or
22 by any other parts of EPA would be an unnecessary and
23 duplicative waste of resources.

24 If what EPA told the EDSP staff is not
25 correct, then EPA should withdraw and rethink its EDSP



1 test orders for atrazine, because they do not do what
2 EPA said they would do.

3 A second point is that EPA's new
4 proposed SAPs have nothing to do with new science.
5 They're all about politics. Atrazine had a clean
6 review from EPA as of July, '09 on the EPA web site.
7 Then, the NRDC published a propaganda piece about
8 atrazine. A dying newspaper, the New York Times, then
9 ran an unbalanced opinion piece based on the propaganda
10 piece by NRDC. And, according to the Huffington Post,
11 Senator Boxer then ordered EPA to go after atrazine,
12 and EPA followed orders.

13 These SAPs are bad politics, and they're
14 a colossal waste of scientific time. EPA hasn't even
15 given this SAP any SAP charges. Consequently, we
16 suggest that the SAP consider making its own charges
17 and tell EPA not to propose any further atrazine SAPs
18 until and unless the Agency can justify them on the
19 basis of EPA-reviewed data that meet Agency quality
20 standards, including the Information Quality Act
21 predissemination review standards.

22 Our third and last point is that various
23 blogs, NGOs, and individuals have attacked the
24 competence and integrity of EPA career staff that have
25 worked on atrazine in the past. Some of their attacks



1 have been directly at named EPA individuals and violate
2 all civilized standards of professional debate.

3 Because EPA's assessment and regulation
4 of atrazine has always been based on review by SAP
5 scientists, these attacks also challenge the competence
6 and integrity of the seven SAPs who have reviewed
7 atrazine over the last 15 years under four
8 administrations, including President Clinton's
9 Democratic administration.

10 We ask the current EPA political
11 appointees to publicly state their competent...their
12 confidence in the competence and integrity of the EPA
13 career staff and the SAP scientists who have reviewed
14 and regulated atrazine in the past. This public
15 statement of support is necessary to protect Agency
16 staff and scientists who are being bullied and to
17 demonstrate that science and civil discourse are still
18 the rule at EPA.

19 Thank you.

20 **DR. HEERINGA:** Thank you very much, Mr.
21 Slaughter.

22 At this point, we have a second public
23 comment presentation which, in agreement and
24 prearrangement with Joe Bailey, the Designated Federal
25 Official, will run a little longer. This is a



1 presentation by Syngenta Crop Protection and includes
2 Janice McFarland, Dr. Janice McFarland, Dr. Peter
3 Hurdle, and Dr. Charles Breckenridge.

4 And if they would like to come forward,
5 and why don't we use these chairs here on the side? I
6 believe there is a presentation set of slides for the
7 panel members that should be in your packet. Dr.
8 McFarland will take the lead.

9 **DR. MCFARLAND:** Thank you, Mr. Chairman,
10 for the opportunity to be here today and to the panel
11 and also to EPA.

12 We look forward to...I'm Janice...I'm
13 Dr. Janice McFarland, and my background is that I
14 started with our company 23 years ago as a metabolism
15 chemist doing guideline studies for...for...in the
16 environmental animal and plant metabolism, guideline
17 studies under EPA.

18 I then in 1994 was the manager of the
19 atrazine, triazine special review at the initiation of
20 that...at the initiation of that review and then stayed
21 involved in the science regulatory process for the
22 triazines since that time. I'm currently...and since
23 2000 have been the head of regulatory affairs for
24 Syngenta for the U.S. and Canada and Mexico.

25 Syngenta, for a little background for



1 those who don't know the company, is a world leader in
2 the discovery and development, registration and
3 stewardship of agricultural tools. We currently
4 steward approximately 75 different fungicides,
5 herbicides, and insecticides. Atrazine we have been
6 the principal steward of for the past 51 years and have
7 greatly appreciated the thorough and comprehensive
8 scientific reviews of that product.

9 I'm happy to be here today with two of
10 our top leading scientists and all who have many, many
11 years of experience on the atrazine safety profiles.
12 They are Dr....to my far left, Dr. Charles
13 Breckenridge. He's a senior research fellow with
14 Syngenta, and he has been the leading mammalian
15 toxicologist and the lead scientist on the mode of
16 action of atrazine.

17 I also have Dr. Peter Hurdle with us.
18 He is Syngenta's head of product safety for the U.S.,
19 Canada, and Mexico and has been the lead environmental
20 exposure and monitoring and characterization scientist.
21 We're all happy to be here today.

22 We'd like to thank the SAP for...I'd
23 like to thank the SAPs for all the contributions on the
24 work and review of atrazine over the last 20 years as
25 well as the extensive work of the Agency scientists



1 who, throughout that process, there's been an
2 advancement of not only basic research but the
3 understanding of safety testing for both atrazine and
4 for all products.

5 The thorough review that's been well
6 documented in the white paper has been going on for
7 some...for 20 years. It's an unprecedented state of
8 the art science data base, and as Dr. Breckenridge will
9 share with you, the regulatory endpoints are
10 conservative and very protective.

11 Independent reviews, you often don't
12 hear about the other regulatory authorities around the
13 world have also confirmed atrazine's safety in recent
14 years, and I'll go over that a little bit, but the
15 process in the U.S. EPA has been very transparent, and
16 since 2000 alone, there have been opportunities for
17 more than 16 public comment periods. And as many of
18 you know and have been involved with, there have been
19 six SAPs alone since 2007 since the re-registration.

20 This time line we don't need to go into,
21 because Dr. Bradbury and also Dr. Levine discussed
22 various aspects of it. This is a time line just
23 documenting all the different work since 2000, the key
24 milestones and key regulatory milestones with the U.S.
25 EPA, and if you go back, it was in the, as they



1 mentioned prior, it was '88 when the re-registration
2 started.

3 An SAP was held in '88. In '88, also
4 health advisory limits were established by the Office
5 of Water, and the NCL was promulgated for the water
6 standard for...was promulgated by EPA's Office of Water
7 in 1991. The special review started in 1994.

8 There are some public comment periods
9 that people don't realize have happened that...that
10 really add to the transparency of the last 20 year
11 review.

12 For instance, if you look at that '02
13 time frame and you see the public technical briefing on
14 atrazine, prior to that, in '01 when EPA completed
15 their preliminary health reviews and the preliminary
16 science...environmental science reviews, those are put
17 out for people to review and there are 60-day public
18 comments. So, throughout this time line, there's
19 extensive opportunity for transparent public comment
20 and information exchange.

21 Around the world, there has been a
22 systematic review. So not only by U.S. EPA, but a
23 systematic comprehensive review by different regulatory
24 authorities, and in this time...this particular graph
25 is focused on the cancer decisions for the



1 International Agency on Research in Cancer. Looked at
2 atrazine in 1999.

3 Different regulatory bodies to look at
4 the registration, the registerability of atrazine and
5 the cancer classification began with the European
6 Union. The United Kingdom was the science rapporteur,
7 and...and they looked at atrazine thoroughly in both
8 '96, 2000, and then again in 2003.

9 The U.S. EPA, we all know here.
10 Canada...Canada just completed their review of
11 atrazine, and they came out with documents in 2003,
12 '04, and then '07. And Australia came out with
13 documents and reports and conclusions of reviews in '04
14 and '08.

15 If you look at the World Health
16 Organization, the last column there, the World Health
17 Organization and the United Nations Food and Ag
18 organizations...that's a joint meeting for pesticide
19 residues...was held in 2007.

20 For all of these different
21 regulatory...regulatory authority reviews and
22 decisions, they determined that it was non- genotoxic,
23 atrazine was not genotoxic, that its mode of action was
24 not relevant to humans, and gave the cancer
25 classification as not likely to cause cancer in the



1 language of the different regulatory, that the
2 different regulatory authorities use. Either not
3 classifiable or not likely to cause cancer.

4 If you...when the reviews are extensive
5 of many different studies. This is one just from the
6 World Health Organization. It documents that the
7 reviews are comprehensive, that the mode of action is
8 well understood, that epidemiology research was
9 reviewed and looked at, that atrazine is non-
10 development...developmental toxicant or and...and it
11 does not cause harm to fetuses, infants, and children.

12 Other quotes just from some of these
13 reviews, often because atrazine is not registered in
14 Europe, people erroneously conclude that that was due
15 to science or health reviews, and that...that is not
16 true. The science and health assessments conducted by
17 European Union authorities, with the United Kingdom
18 being their science rapporteur and France also held
19 their own review, all determined that atrazine could be
20 safely used. And so, the quote from France, they don't
21 represent a public health. The United Kingdom, that
22 atrazine can be used without harm to animal health or
23 the environment.

24 And then, the most recent regulatory
25 authority review around the world outsi...since the



1 cumulative risk assessment conducted by EPA in 2006 was
2 done by the Australian regulatory authorities and
3 determined that atrazine was not...not carcinogenic and
4 also did not have developmental effects and could be
5 safely used as a weed control tool.

6 With that as a backdrop, I'm going to
7 turn over the...turn over the presentation to Dr.
8 Breckenridge who is going to give a brief overview of
9 the human safety assessment of...of atrazine.

10 **DR. BRECKENRIDGE:** Thank you, Janice.
11 My name is Charles Breckenridge. I'm a senior research
12 fellow with Syngenta. I have been involved with the
13 atrazine safety profile and exposure characterization
14 for more than 22 years now.

15 We at Syngenta were the first ones to
16 discover that atrazine caused mammary tumors in 1986,
17 and since that time, we have been working with a group
18 of outside researchers to assist us to understand the
19 processes associated with the cancer response in
20 animals and, subsequently, other...other effects that
21 we have proposed as the mode of action underlying that
22 tumor response.

23 Some of my colleagues that are not here
24 with me today and who have contributed substantially to
25 the development of knowledge on atrazine include the



1 head of our endocrinology team, Dr. James Simpkins.
2 He's from the University of North Texas, and you all
3 have probably met him at earlier SAPs.

4 Dr. Robert Handa who's at...now at the
5 University of Arizona, previously at Colorado State
6 University, has continued to work on the mode of action
7 relative to the effects on GnRH neurons. Dr. Russ
8 Holvey from the University of California Davis is
9 working with us today, currently on mammary gland
10 development studies.

11 Evan Simpson is an aromatase expert from
12 Prince Henry Institute in Australia, is working with us
13 on stereogenic factor 1 and the postulate that atrazine
14 regulates that factor and is responsible for aromatase
15 expression. Jack Mandel, who's served with us on a
16 number of epidemiology SAPs, particularly, the
17 prostate cancer SAP, and has also done a critical case
18 control study at our production facility relative to
19 prostate cancer.

20 Jim Slinberg is an expert in weight of
21 evidence characterization now at the University of
22 North Carolina, Chapel Hill, has also been working with
23 us over the years, and undoubtedly, you will hear from
24 all of these gentlemen as we move forward with...with
25 new data as it pertains to questions that are raised by



1 the EPA and the published literature.

2 For today, we intend to...to not take
3 our standard approach of presenting data and reasoned
4 logic and reaching conclusions. Rather, we intend to
5 sort of summarize in a captioned way what has been
6 known as we've gone through the development of
7 knowledge on the atrazine hazard profile, exposure
8 characterization and risk.

9 So, that is not the way we will operate
10 in subsequent SAPs. We will present data. We will
11 reason through logic, and we will reach scientific
12 conclusions, and, hopefully, you'll concur with our
13 interpretation of our own data and other data, but for
14 today, we're just going to summarize in a nutshell what
15 we believe to be true based on more than 22 years of
16 research on atrazine.

17 And I should say, just as a...a
18 first...they don't seem to be advancing...okay...so
19 that we will give just a brief description of the
20 comprehensive database that exists, the safety profiles
21 that have been characterized, the safety standards that
22 EPA has endeavored to set based on the effects that
23 have been observed with atrazine in animal models, and
24 the perspective of exposure relative to those safety
25 standards, especially as it pertains to exposure via



1 drinking water.

2 This slide represents a...a picture
3 of...of our database within the company, and each of
4 these is not necessarily a single study, but it
5 represents a project, and it comprises areas of study,
6 including herbicidal properties, physicochemical
7 properties, environmental fate transport, environmental
8 effects, toxicity, mode of action, metabolism,
9 kinetics, dynamics, risk assessment methodologies. So,
10 that over the course of...of near 50 years, many
11 studies have been conducted, and some of those have
12 been brought forward and have shown to be greatly
13 critical for this risk characterization for atrazine.

14 Other people have, obviously, developed
15 an interest in atrazine as well. In the public domain,
16 we keep track of published...any new published studies
17 as, apparently, others do, and we note that there is an
18 exponential growth in publications. We do pay
19 attention to that literature, and to the extent that we
20 see a study has implications that are critical for the
21 human safety, we endeavor to investigate those studies
22 and perhaps even try to replicate them and understand
23 what they're telling us.

24 These are in vitro, in vivo, mode of
25 action across the whole spectrum, and that's basically



1 our strategy of continuing to keep updated on what is
2 happening in the literature relative to atrazine and
3 whether or not the concepts that are developing in the
4 literature that are at odds with the regulatory
5 standards are our own perception of...of what atrazine
6 does.

7 Now, in regard to regulatory standards,
8 obviously, Syngenta and other registrants are obligated
9 to provide specific high-quality studies that are well
10 documented in terms of standards of excellence, and our
11 database on atrazine has repeatedly grown and been
12 updated as new concepts and new protocols have been
13 developed and new approaches have been taken. In the
14 areas of mutagenicity, we have within our own database
15 and within the published literature, there are more
16 than 50 studies.

17 When I speak of atrazine, I speak of
18 atrazine in the mono and dealkylated metabolites as
19 well as hydroxyatrazine, because effectively, EPA
20 reached a conclusion which we concur with that atrazine
21 should belong to a common mode of action group with the
22 chlorotriazines, and so, when you speak of atrazine,
23 you should speak of the chloro metabolites. We did
24 lifetime studies on hydroxy metabolite as well which
25 happens to be a...a major plant metabolite, and we



1 demonstrated that it, in fact, had a different mode of
2 action distinct from the chlorotriazines.

3 So, in the course of studies that we've
4 done, we've done full databases or part databases on
5 the metabolites and as well as the parent. We've done
6 mode of action studies in parent and we've done cross-
7 over studies to metabolites so we can appreciate, in
8 fact, where the toxicity might be coming from.

9 You should be aware that for a human
10 that is exposed to atrazine, atrazine's half-life in
11 the body is very short. It actually gets converted
12 very quickly to the dealkylated metabolites and
13 conjugated metabolites so that, in fact, the issue
14 isn't atrazine. It's...it's the biotransformation
15 products in the body, and we've been involved in that,
16 in those investigations.

17 Overall mode of action work on the
18 cancers led us to the first question, is it
19 carcino...is it a mutagen, and the answer seems to be
20 resoundingly clear that it is not, and that is pretty
21 well, from our viewpoint, no matter how many additional
22 studies might or might not get published, is off the
23 table as a serious consideration for its mode of
24 action.

25 We have studied whether atrazine

1 directly mimics estrogen, androgen, or the thyroid
2 hormone. EPA's own research lab has been very much
3 involved with this work. There are now more than 40
4 published studies on whether atrazine has estrogenic or
5 anti-estrogenic properties, and in 2008, Aldridge,
6 et.al. reviewed those studies and wrote up a...a weight
7 of evidence on that. The conclusions are that atrazine
8 does not operate as a direct hormone mimic in any of
9 these vectors, and these are the principal targets for
10 the endocrine disruption screening.

11 I think in 1994 when we first began this
12 work, we kind of predated the concern for endocrine
13 disruption. It turns out that atrazine had a mode of
14 action relating to the endocrine system. We discovered
15 that and today, I think, we're hearing a lot more
16 interest in potential chemicals to do with effects on
17 the endocrine system.

18 As has been stated, the cancer mode of
19 action has been well characterized. We've been
20 involved with that research over the years. So has
21 critical labs in EPA's ORD. And from these studies
22 have been developed the critical no effect levels that
23 currently set the standard of exposure to atrazine, and
24 this is based on the suppression of luteinizing hormone
25 which was mentioned as a surrogate for the endocrine



1 effects of atrazine.

2 Just so briefly we can say what
3 that...that comprises is that atrazine seems to
4 modulate the GnRH neurons which are a small set of
5 neurons located in the preoptic area in the
6 hypothalamic region of the brain. They are pulse
7 generators that lead to pulsatile release of GnRH which
8 travels to the pituitary and causes LH and FSH actually
9 to be released.

10 These have effects on the gonads,
11 especially in females, to...to lead to ovulatory events
12 and, in males, to regulate testosterone levels. And
13 these processes play a critical role during onset of
14 puberty in the sense that GnRH pulse generator plays a
15 role in puberty onset as well as regulating
16 reproductive function in the adult animal.

17 So, the LH suppression that we see with
18 atrazine at high doses is actually a decent surrogate
19 for its effects on the endocrine system. We've been
20 working with Dr. Handa for a number of years to try to
21 understand precisely how and where atrazine operates on
22 the GnRH system, and you'll hear more about that
23 research in...in subsequent meetings.

24 **(W (WHEREUPON, there was a pause in the proceedings.)**

25 **DR. BRECKENRIDGE:** So, the LH endpoints

1 that EPA utilized for short and long-term duration
2 exposures in their 2006 chlortriazine cumulative risk
3 assessment, I will focus on two of them. The first one
4 is the...for covering 90-day exposures and exposures
5 that extend throughout a lifetime. This is based on an
6 LH effect, that is, LH LH suppression in the Sprague-
7 Daly rat at 6 months of age or at 6 months of dosing, I
8 should say, and this represents a no effect level, a
9 1.8 milligrams per kg with 1000-fold uncertainty
10 factor, including a 10x FQPA factor leads to a
11 reference dose of 0.0018 mg/kg, and that is the basis
12 for what we believe would be an acceptable standard for
13 setting the...the chronic exposure to atrazine in
14 drinking water. We'll come to what the current
15 standard is in a minute.

16 The second endpoint that was selected
17 was 6.25 mg/kg no effect level from a study by Tammy
18 Stoker in the ORD, a group in Research Triangle Park.
19 She was studying a surrogate for LH suppression. She
20 was looking at preputial separation in males, that is,
21 the onset of sexual maturation in males which is
22 dependent on testosterone and, in turn, dependent on LH
23 release. She established a no effect level in this
24 study, and this was about a 20 or 30-day study.

25 We have taken the liberty of plotting



1 the various studies available in the literature that we
2 could find on the Sprague-Daly rat in terms of duration
3 of dosing and effect on LH. So, these NOELs are
4 actually LH no effect levels in animals at different
5 durations of treatment. So that Ralph Cooper has done
6 a study in 2000 where he dosed animals for either 1
7 day, 3 days, or 21 days.

8 The no effect level for effects on the
9 LH system at 1 and 3 days was 300 mg/kg. We have
10 recently, through collaborators in Dr. Handa's lab,
11 published a study with Fidori that the no effect level
12 for, I believe it was, a 4 or 5-day treatment was
13 around about 100. Cooper at 21 days showed it was less
14 than 100. Our own study, Morrisette in 1996...I think
15 that was a 28-day study, Stoker's around about 21 days,
16 at 6.25 mg/kg, and as I stated, the Stoker study
17 actually sets the short-term reference dose for
18 atrazine in regard to the LH effect.

19 And, finally, the long-term LH effect.

20 Now, you may think that this actually
21 represents continuous effects of atrazine treatment on
22 this LH system, but, in fact, it actually simply might
23 reflect that the neuroendocrine system is very robust
24 in the young adult animal, and as Sprague-Daly rats age
25 endocrinologically, it becomes progressively damaged as



1 a result of continuous estrogen exposure.

2 It actually damages the arcuate nucleus
3 and its regulatory process so that, in fact, this might
4 simply reflect age-dependent deterioration of a control
5 mechanism in the brain, and one would need a special
6 set of studies to...to illustrate that point.

7 So, the aspect of the young being more
8 sensitive in regard to this effect, it does not seem to
9 be supported by existing data where the actual aged,
10 endocrinologically aged animal has the lowest no effect
11 levels, whereas the young animals tend to have less of
12 a response.

13 Nevertheless, we come to finally taking
14 those endpoints and establishing standards for drinking
15 water, and the Agency has expressed concern about have
16 we been able to properly characterize the frequency or
17 the...the spikiness of atrazine exposure in drinking
18 water. So, the postulate would be that somehow during
19 a runoff event in agricultural season, we would miss a
20 critical peak if we hadn't had very frequent
21 monitoring.

22 But put that in the context of the
23 actual no effect levels in single day NOELs and we
24 derive DW LOC, you can see that, in fact, in the short
25 term, the animal tolerates the...the dose much better.



1 So that single-day developmental NOEL, the Agency
2 actually didn't use LH. They used a developmental NOEL
3 from a rapporteur ecology study which is 13 days of
4 treatment. That NOEL is 10 mg/kg.

5 The Stoker study for 30 days at 6.25,
6 and the MCL was set in 1991 based on a chronic dog
7 study where, in fact, that no effect level has been
8 outdated to a...a higher level. That MCL, basically,
9 has been in need of updating for...for more than 25
10 years.

11 Today, under the TCT cumulative risk
12 assessment, EPA reached a viewpoint that 1.8 mg/kg is
13 the no effect level of record for the most sensitive
14 species in strength, and if you take that into a child,
15 a child's body weight and water intake, you get a
16 standard of 12.5 ppb considered to be safe in drinking
17 water for lifetime exposure.

18 Those limits are brought forward to you
19 today so that you can see them in the context of the
20 subsequent presentation by Dr. Hurdle who will
21 characterize the presence and amount of atrazine in
22 drinking water over the course of many years of
23 monitoring. So, with that, I'll turn the lectern over
24 to Dr. Hurdle unless there's any questions. Dr.
25 Hurdle?



1 **DR. HEERINGA:** I think we'll wait. Thank
2 you, Dr. Breckenridge. Dr. Hurdle?

3 **DR. HURDLE:** My name is Peter Hurdle. I
4 thank the panel for the opportunity to comment, and
5 without much ado, I would like to jump into the next
6 slide which is entitled comprehensive drinking water
7 exposure assessment.

8 And very much like the presentation that
9 Dr. Breckenridge gave about the number of studies that
10 have been conducted, I have to say that drinking water
11 exposure has been characterized by a huge number of
12 research teams which include our own internal Syngenta
13 research efforts, and we'll be speaking about that in a
14 couple of minutes but also includes a huge body of data
15 that has been generated under the Safe Drinking Water
16 Act by the states, by universities, by academia, and by
17 other research organizations.

18 So, what I will try to show you in the
19 next couple of minutes is the comprehensiveness of the
20 monitoring database, that impact exists and has been
21 generated over the last 20-plus years. The...our
22 ability to fully define the exposure protocols
23 that...that consumers are potentially exposed to, we
24 will actually show you that the current drinking water
25 exposure levels demonstrate that we do achieve a large



1 margin of...of safety, and we will also show you that
2 the stewardship measures that have been undertaken over
3 the last 15 years since the mid '90s, the label change,
4 the setbacks and other mitigation language
5 effectively...have been quite effective in reducing
6 environmental concentrations in both well and finished
7 water.

8 So, if you...if you look at databases
9 for drinking water exposure, data are generated, first
10 and foremost, are the state drinking water monitoring
11 programs which are community water systems that ensure
12 quality control in their drinking water supplies to
13 their consumers. You have about 51,000 community water
14 systems in the...in the United States. About 40,000 of
15 them are community systems and groundwater.

16 If you look at the actual analytical
17 record that has been generated since '93, to date,
18 there are about 212,000 samples analyzed in those
19 programs. These are all finished drinking water, and
20 the bottom line is that detects in groundwater systems
21 are extremely infrequent. Less than 1 percent of the
22 system has a detect of atrazine, and if you find it,
23 it's very low. The resulting, resulting margins of
24 exposure greatly exceed 20,000.

25 The margin of exposure would be here.



1 The actual maximum concentration people might be
2 exposed to in a day or chronically as compared to the
3 no effect level that was established for the
4 appropriate time period.

5 Which leaves us about 11,000 systems on
6 surface water that do provide drinking water to, in the
7 United States. Again, all these 11,000 systems were
8 candidates for drinking water monitoring under the Safe
9 Drinking Water Act, and they do sample finished water.
10 They typically take quarterly samples, so four samples
11 per year, sometimes less, and most of the systems that
12 are in areas of potential high atrazine exposure have a
13 record of about 16 years of data, because they
14 initiated the sampling program in 1993 and it's still
15 active today.

16 So, this is the...the state database.
17 The state database is supplemented by two high
18 intensity sampling monitoring programs. The first one
19 was voluntarily initiated by Syngenta in 1993 and
20 continued until February, 2003. It included the most
21 vulnerable community water systems that were producing
22 surface water and supplying it as drinking water,
23 mainly in water systems in the Midwest and in the
24 South. We had up to 120 community water systems in
25 that program.



1 It was a high sampling intensity
2 program. It took between 40 and 60 samples per year in
3 both raw and finished water which enabled us to fully
4 characterize exposure protocols in the raw waters as
5 well as in the finished water supply to consumers.

6 This program was replaced in spring of
7 2003 by the atrazine monitoring program which was a
8 condition of the MOA Dr. Bradbury referred to earlier,
9 and we have now a formal entry criteria for systems
10 joining the monitoring program which was more
11 conservative. Any system that had a single exceedance
12 of 2.6 ppb total for triazines. AMP also looks for
13 metabolites which is about the equivalent of 1.6 ppb
14 atrazine joins the system.

15 And so, that program then included up to
16 151 community water systems in intensive monitoring.
17 Took about 64 to 70 samples per year in both raw and
18 finished water, mainly weekly and also some bi-weekly
19 sampling during Q3 and Q4 and Q1. So, in a nutshell,
20 if we look at surface water systems which are the ones
21 with potential exposure to atrazine, we have a subset,
22 a small percentage, of the high...most highly exposed
23 systems in the U.S. under a high frequency, continuous
24 monitoring program.

25 Systems will stay in the program for a



1 minimum of five years period.

2 So, what did we get from those programs?

3 I summarize quickly the Safe Drinking Water Act
4 monitoring program time record 1993 to '08. We have
5 data for 47,000 community water systems. That's both
6 ground and finished water. We have 212,000 samples in
7 groundwater. We have 68 samples in finished surface
8 water.

9 This data set is complemented by
10 Syngenta's intensive monitoring data which included up
11 to 151 vulnerable community water systems in a year.
12 It looks into raw and finished. Both programs
13 generated 64,000 finished surface water analyses in the
14 most highly exposed systems.

15 Now, in a nutshell, if we look at the
16 finished water samples, none of the more than 340,000
17 data we have on record from finished drinking water
18 exceeded 100 ppb ever. By that, they didn't exceed the
19 209 ppb that Dr. Breckenridge mentioned earlier for
20 short-term exposure as DW LOC. They did also not
21 exceed the 298 ppb DW LOC that was published by EPA in
22 their 2003 IRED.

23 If you look at it chronically, no
24 community water systems in the AMP program which
25 includes the most vulnerable systems with a very high



1 sampling frequency has exceeded 3 pb as an annual
2 average in finished water since 2006.

3 So, we strongly believe that drinking
4 water supply is safe.

5 Now, if we look at effectiveness of
6 label changes and mitigation, what I'm giving you here
7 is a view on the most vulnerable systems, surface water
8 with high intense monitoring, so this is very precise
9 data, and what we see here is the overall average of
10 atrazine concentrations between 1994 and 2008. The
11 years between '94 and 2002 are the voluntary monitoring
12 program, and then we have the AMP which includes a few
13 more systems.

14 So, what we see, that overall in those
15 most vulnerable systems, finished water concentrations
16 were at about 1.5 ppb in the mid '90s, and they
17 consistently declined and have reached a level of about
18 0.5 ppb in finished drinking water by 2008.

19 If we look at well water in those same
20 systems...we also took well water samples, high
21 frequency...we see a very similar trend. We see a high
22 level in the early '90s in well water which does not
23 quite reach 3 ppb on average, and we see a consistent
24 decline to levels just below 1 ppb.

25 So, both in raw and in surface water, as

1 a total average in those systems that are the most
2 highly exposed in the U.S., we have had a 60 to 70
3 percent decline in concentrations in well water as well
4 as in...as in finished water.

5 Peaks have been quite a bit of
6 discussion and hype recently, and we do believe that we
7 actually have a second program in place that gives us a
8 good view on what peak concentrations could potentially
9 be and how peaks could be characterized. This is the
10 eco monitoring program that I'm referring to. Dr.
11 Bradbury mentioned it as well as one of the conditions
12 of the memorandum of agreement.

13 This is not drinking water. I am giving
14 you here a little snapshot result. You might have seen
15 this slide already. So, these are 45 watersheds in
16 highly vulnerable settings, ecologically very
17 vulnerable and with high atrazine use volume. We look
18 in second and third order headwater streams, so these
19 are not drinking water water bodies, but they might
20 feed into some.

21 That program was initiated in 2004 and
22 is still active today. We have over 10,000 samples
23 analyzed. And the program was set up to focus on the
24 run-off seas, and we run it for about four to five
25 month right after the atrazine application season, so



1 we have a very good profile and characterization of
2 potential exposure peaks.

3 This program has generated 190 site
4 seasons of well resolved concentration time profiles
5 for atrazine. Again, this is not drinking water, but
6 the data, sampling data, we believe, can be used to
7 serve as a worst case surrogate to describe peaks.

8 What do we see in those programs? Let
9 me quickly talk about the eco monitoring program which
10 is in the left upperhand box. We have about 10,000
11 data points. We have had a sampling schedule in 2004
12 and 2006, four days, grab samples. This was
13 supplemented at about 25 percent of the sites with
14 autosamples which were event driven.

15 And then, in 2007, we changed the
16 program in order to be able to better describe peak
17 concentration profiles to a daily sampling program.
18 So, 2008, '07, 2008, 2009 generates data...daily
19 samples, very tight time resolution.

20 This data set is, again, supplemented by
21 a huge database that is available and has been
22 generated over the last 40 years in surface water
23 bodies. These are mainly studies that both were done
24 under the USGS's monitoring program and other USGS
25 programs. Heidelberg College has done a substantial



1 body of work.

2 Most of these programs were sampled on,
3 the ones you see were sampled on characterizing runoff
4 events. So, what did we see in those almost 120,000
5 environmental samples over the last 20 years?

6 We see that we have the peaks well
7 characterized. We have a large body of data that is
8 available for analysis, and we have never seen an
9 exceedance of the 298 ppb drinking water level of
10 concern in any of those environmental monitoring
11 programs.

12 So, let me quickly talk about the
13 concentration frames. You have seen this slide before.
14 This is the overall average concentrations in the
15 high...most highly exposed systems that grew in the
16 voluntary monitoring program and the atrazine
17 monitoring program.

18 If you analyze those data a little bit
19 more thoroughly as statisticians would do and take
20 only those community water systems that have a
21 continuous record of at least nine years and reported
22 both programs, you do get a highly significant
23 statistical trend that shows you that concentrations in
24 those systems have been declining between 1994 and
25 2006, and they have been declining more for systems



1 that were more highly exposed in 1994 than for a group
2 that never exceeded an MCL of 3 ppb in 1994 and later.

3 Overall, the numbers are quite the same.
4 We see a decline of about 60 percent to 70 percent in
5 '06 relative to the baseline that we have in the mid
6 '90s, and this was achieved without reducing the use
7 volume of atrazine in those areas where these systems
8 are located. So, the line at the top of the graph is
9 the actual use volume of atrazine in those years.

10 Now, what that...what does that mean in
11 terms of margins of exposure and...and human safety?
12 What I, you know, give you here on this slide is an
13 attempt to describe the worst case margin of exposure
14 resulting from a single day exposure based on the data
15 we have generated. So, you have the single day no
16 effect level of 10 mg/kg/day which EPA used to define
17 short-term exposure drinking water level of concern
18 with a safety factor of 1000. You get...and the
19 appropriate body weight and intake numbers. You get a
20 concentration of 298 ppb.

21 What you have on the bottom right-hand
22 of the graph is the probability of this situation of
23 all samples that was generated in the AMP and BMP
24 finished drinking water monitoring program. So, this
25 is the full distribution of all the data, single day



1 values that were measured in those programs in finished
2 water.

3 And if you do a margin of exposure
4 calculation to be a single day no effect level, the
5 resulting margin of exposure is in excess of 10,000 at
6 the 99.9 percentile. If you do the same exercise for
7 chronic and, just for simplicity's sake, I took the
8 median here and compare it to the chronic no effect
9 level of 1.8 mg/kg/day and the safety factor of 1000
10 which leads you if you want to reference those, if you
11 look at the actual exposure resulting in the
12 most...resulting from the most vulnerable systems,
13 we're talking a margin of exposure as in excess of
14 200,000.

15 Please keep in mind these are the most
16 vulnerable systems where you see exposure in drinking
17 water.

18 So, in summary, we have a huge
19 monitoring database. We have about 340,000 finished
20 drinking water samples and 60,000 samples in ground
21 water. We have 118,000 environmental water samples.
22 We have broad geographic and temporal coverage in that
23 data set. We have high sampling frequency in a
24 significant number of data sets which is focused on
25 monitoring locations. You have well characterized



1 peaks in runoff events based on daily sampling.

2 And if you take those data and put them
3 into context of current no effect levels, all those
4 data indicate that we have large margins of exposure
5 which are in excess of 10,000. What we also see is
6 that the label changes actually did have an effect. We
7 had significant reduction in environmental
8 concentrations. This is not only our own data. Also,
9 USGS and state monitoring studies show that.

10 And with that, I hand it back to Dr.
11 McFarland.

12 **DR. HEERINGA:** Thank you, Dr. Hurdle.

13 **DR. MCFARLAND:** The concerns about the
14 process for this SAP are documented in our written
15 comments that went into the docket, but as...but we
16 know that it's an unusual situation for both the SAP to
17 be in as well as us, because normally, we're providing
18 basic research, data information that is actually
19 addressing charge questions or specific reviews of
20 scientific assessments, and in this case, we...we
21 strongly feel that the new information that has been
22 sparked by the attacks of the anti-atrazine group and
23 also in the press do not justify opening a
24 comprehensive re-review of atrazine.

25 But we are...we do remain confident and



1 will be really working hard, committed to fully and
2 openly to contribute in the scientific process that lie
3 ahead. We do ask that EPA be accountable for the
4 scientific integrity of the pro...the regulatory
5 review, and we appreciate and thank the SAP to help
6 ensure that...that it goes through a scientifically
7 rigorous process.

8 We have an unparalleled commitment to
9 advancing the research in the safety assessments and
10 stewardship of atrazine, and the past comprehensive
11 reviews, we're appreciative of all of the efforts that
12 went into those. It is an unprecedented data set on
13 all levels of...of toxicology, risk assessment,
14 exposure, and...and health assessments.

15 The regulatory endpoints, as you saw
16 from both Dr. Breckenridge and Dr. Hurdle, are
17 conservative and protective. They're...we are...we
18 feel very fortunate and blessed, actually, to be part
19 of such a transparent, open review process that has
20 gone on for this product, and we also appreciate all
21 the work from the past SAPs.

22 People, as I mentioned, often forget
23 that the favorable registration decisions or safety
24 assessments were...were not...not concluded only by EPA
25 but by regulatory authorities around the world, and we



1 look forward to...to contributing science throughout
2 the next part of this process, and are happy to
3 entertain any questions from the panel now or if there
4 are other questions after other public commenters.

5 **DR. HEERINGA:** Quick opportunity for
6 panel members to ask questions of clarification of the
7 Syngenta representatives. Dr. Bucher?

8 **DR. BUCHER:** John Bucher. Just out of
9 curiosity, the specific technical part of water
10 disinfection that would reduce atrazine levels,
11 what...what can you tell me about that?

12 **DR. HEERINGA:** Dr. Hurdle?

13 **DR. HURDLE:** Well, as you probably could
14 glean from the slides, there is an effect of water
15 processing. As you process a lot of raw water to
16 finished water, you see reduced levels in those
17 finished water sources.

18 Therefore, I have...however, I have to
19 point out so that there is an effect of water
20 processing, water processing technologies do reduce
21 atrazine levels. However, one of the remarkable points
22 is if you look at the MCL which is the current standard
23 that even the most exposed systems, on average, you do
24 see that in all those sources, an average of far below
25 that...that...that MCL to date which was wholly a



1 consequence of, you know, all the label changes that
2 have been in the last 15 years.

3 **DR. BUCHER:** Thank you, but that wasn't
4 exactly quite what I was asking. The aspect of the
5 drinking water disinfection byproduct or the
6 disinfection process that reduces atrazine levels, do
7 you know what that, technically, what that might be?

8 **DR. HEERINGA:** Dr. Breckenridge?

9 **DR. BRECKENRIDGE:** I don't believe I
10 could comment on the effect of disinfection byproducts
11 modulating atrazine concentration. We know that the
12 carbon filtration systems will modulate atrazine
13 concentrations, if that's what you're getting at, but
14 disinfection byproducts and their presence really
15 don't...

16 **DR. BUCHER:** No, I'm sorry, I misspoke.
17 I have that on my mind, because we deal with that all
18 the time.

19 **DR. HEERINGA:** Dr. Hurdle?

20 **DR. HURDLE:** Well, I have just one add
21 on to it. While we do know the hydrology stability
22 under different pH conditions of atrazine, but...you
23 know, and that's evident, so, there is data available
24 that, you know, might instruct to that, but I'm not
25 prepared to, you know, answer that question right away.



1 **DR. HEERINGA:** Dr. Portier.

2 **DR. PORTIER:** You talked a lot about
3 community water systems. Has there been any
4 measurement of...of well water, non-community water
5 systems, residential wells in rural areas where there
6 would be vulnerability?

7 **DR. HURDLE:** We have, in fact, done a
8 pretty comprehensive rural well monitoring study in '92
9 to '94. We sampled about 1505 rural wells, if I'm
10 correct, recall that correctly. We analyzed the well
11 water for both atrazine and atrazine metabolites, and
12 that data are available and have been related by EPA,
13 so they're part of the atrazine database.

14 We did some resampling campaigns in 2000
15 and then again in 2007 to look at the most vulnerable
16 wells and that could confirm exactly the same trend
17 that you have seen here with the surface water systems.
18 Levels have been declining significantly and
19 consistently.

20 **DR. HEERINGA:** Okay, I'd like to move
21 on, but I'd like to also thank Syngenta representatives
22 for their presentation. Thank you.

23 Our next scheduled public commenter is
24 Dr. Jennifer Sass who is representing the National
25 Resources Defense Council. Jennifer, are you here?



1 Jennifer...Dr. Sass, are you here?

2 (No response.)

3 **DR. HEERINGA:** Not seeing Dr. Sass, we
4 will move on to Dr. Joel Nelson who is representing
5 California Citrus Mutual. Dr. Nelson? Take this chair
6 where the mike's lit up there, if you want.

7 **MR. NELSON:** Well, thank you, ladies and
8 gentlemen for this opportunity to participate in
9 another SAP. For the record, I'm not a Ph.D., not a
10 doctor. I'm not a lawyer, either, so I think I'm in
11 pretty good shape.

12 My name is Joel Nelson. I'm president
13 of California Citrus Mutual which is a citrus
14 producers' trade association from California.

15 Now, you're probably wondering why I'm
16 here, and last night or yesterday afternoon as I was
17 flying into Washington, I was wondering the same thing.
18 Been here, done that on several occasions, in my
19 particular case, about four times relative to atrazine.
20 But our industry is a user of simazine, a derivative of
21 atrazine. And as goes atrazine, so goes simazine, and
22 we know that.

23 So, a number of years ago...and our
24 chairman will be testifying shortly...agriculture
25 across the country formed an entity called the Triazine



1 Network, and we became part of the steering committee,
2 and we began working with colleagues across the country
3 on this particular issue, because we felt we had a
4 responsibility, a responsibility to address the
5 concerns, the legitimate concerns associated with
6 herbicide use in agriculture.

7 For our industry, the citrus industry,
8 we are weed free. We have to be. Our fruit stores on
9 the tree. It constitutes a problem when weeds are
10 pervasive in a grove. Creates a home for invasive
11 pests, but just as importantly if not more so, we keep
12 our groves warm without weeds by running water and wind
13 machines. Weeds will make a grove colder by 3 to 4
14 degrees, according to scientific studies at the
15 University of California.

16 So, it's in our best interests to keep
17 our groves weed free. We don't till. Warmth is a
18 serious, serious issue for us in the months of November
19 15th through, roughly, March 1st.

20 So, simazine has become an important
21 product for our arsenal and our growers, 38...3500
22 producers, 285,000 acres, \$1.8 billion worth of
23 product. We're the number one citrus producing state
24 in the nation. We got that way because of disease in
25 Florida. They've lost their value. Ours continues to



1 increase, and we're proud of it.

2 But as I flew back here again, ladies
3 and gentlemen, I wondered, why are we here again? And
4 I was struck by the similarity of the occurrence in
5 reading the documents from EPA. I was around when
6 Fenton Communications started the Alar situation in
7 public relations.

8 I was around when we had an adverse
9 kneejerk effect with that public relations fiasco. It
10 took a long time for the public relations industry to
11 recover their credibility as a result of that, and
12 there were a lot of chastened individuals as a result
13 of that entire episode.

14 And I was around and went and saw Straw
15 Dogs with Al...Al Pacino, and I remember what happened
16 in that particular movie.

17 Well, ladies and gentlemen, as I read
18 the documentation creating this effort, knowing that we
19 have gone through this so many times and we're
20 scheduled to go through it again under a normal
21 process, why are we here again?

22 Well, we're here because government
23 asked us to participate once again in a science
24 advisory committee. So, all I say to you now is that
25 the citrus industry from California, Citrus Mutual will



1 participate where appropriate.

2 I will admit I don't understand three-
3 fourths of what you just...three-fourths of what you
4 just heard. I'm a policy person. I can read
5 conclusions. I have read your conclusions at EPA.
6 Atrazine is safe. I have read your conclusions for 14
7 years. Atrazine, when used according to the label
8 restrictions, is safe. I've read it relative to water.
9 I've read it relative to carcinogens.

10 I've read it over and over and over
11 again, and I'll wait for a conclusion, and I'll
12 participate in a process, because that's what this is
13 all about. It's another process. Let's be honest
14 about it.

15 So, we have an obligation to
16 participate, but on behalf of the citrus industry in
17 California, you know we will be here. Again, when
18 appropriate, call upon our industry, but please, don't
19 ever address me as Doctor, because I can't wear that
20 hat.

21 Thank you very much.

22 **DR. HEERINGA:** Thank you, Mr. Nelson.
23 Somebody felt you earned it, but we'll track them down.

24 Our next public commenter is Gary
25 Marshall who is here today representing Missouri Corn



1 Growers Association. Gary?

2 **MR. MARSHALL:** Thank you, Mr. Chairman.

3 It is, I guess, good to be back here again. Seems like
4 I was just here a couple of months ago, maybe three
5 months ago, whenever it was, in June.

6 Again, my name is Gary Marshall, and I'm
7 the CEO for the Missouri Corn Growers Association, and
8 I also serve as chairman of a group that we have in
9 Missouri called the Environmental Resources Coalition,
10 ERC.

11 Environmental Resources Coalition
12 is...is a group that we helped put together along with
13 several government entities, including our Department
14 of Natural Resources, the University of Missouri, a
15 number of farmers in the State of Missouri, the farmers
16 that I represent. And we used, over the years, some of
17 EPA's 319 dollars to help address some of the areas of
18 concern that we're talking about today, and talking
19 about it again today, I must say.

20 You know, we have about 15,000 growers
21 in the State of Missouri and over 300,000 farmers
22 nationwide who utilize atrazine as a product.
23 And...and I realize this is more about the science, but
24 there's also the user community out there which I
25 represent.



1 In Missouri, we use it on over...between
2 3 and 3.5 million acres, because the product works.
3 It's better than anything else that we have access to
4 today. Combining atrazine with other herbicides allows
5 us to minimize weeds which compete for the nutrients
6 and the water in our soils.

7 Beyond that, I have about 15 years'
8 worth of experience in utilizing atrazine. In a
9 previous life, we spread probably in excess of 200,000
10 acres over a 6 to 8-year period as a commercial
11 applicator. So, I've utilized atrazine. I've utilized
12 other products that are out there. I know what it
13 does, and I know that it works.

14 And the farmers in Missouri tell us that
15 it does work. It continues to work. In fact, in the
16 last survey that we had, about \$60...or \$20 per acre,
17 \$60 million worth of savings by utilizing atrazine
18 instead of switching to another product that doesn't
19 work as well and that has a higher cost.

20 So, bottom line, it's right and
21 appropriate for us to engage in this process. And
22 we've submitted comments previous to this, and I'm not
23 going to read those comments, but, you know, Halloween
24 was just a few days ago, and it almost feels like
25 Halloween again. Here we are again one more time.



1 It...it's scary, because I'd like to know when is
2 enough enough.

3 You know, I've worked with scientists
4 back in our state, and sometimes, 98 percent is good,
5 and sometimes, 99 percent, and sometimes, I think here
6 we're talking about 99.89, 99.92 percent. When is
7 enough enough? We've got thousands of studies now, over
8 6000 studies, I think, reams of paper. I think the
9 agreement is out there.

10 In fact, let me read just a quote to you
11 that...that we found in EPA's own web site, and that
12 is, the Agency has found that there is a reasonable
13 certainty that no harm will result to the general U.S.
14 population, infants, children, or other major
15 identifiable subgroups of consumers from aggregate
16 exposure from food, drinking water, and non-
17 occupational sources to cumulative residues of atrazine
18 and the other chlorinated triazine pesticides.

19 Now, that's what we go on. We trust the
20 EPA. There's a process here that we've been involved
21 with for a number of years. As...as Joel just
22 mentioned, I'm going up, I think, on 14 years with the
23 triazine network as a steering committee member, 13 or
24 14 years. I think it's been around for 15 years. And,
25 again, I would say, when is enough enough?



1 We think that the science is there.
2 We've seen it. We've looked at some of the new science
3 that's out there. We don't believe that it tells us
4 that we need to be looking again at more science.

5 So, I guess my comments would be that
6 there's nothing new. This is kind of unprecedented. I
7 think it's being driven by some folks out there that
8 are anti-farming. They're anti-agriculture, and if
9 that's true, you own it. If it is an activist agenda
10 that is to ban all pesticides, well, we're going to be
11 here. Just like Joel, we're going to be here. We're
12 going to fight that.

13 We're going to use our connections
14 wherever we have them to...to get our point across,
15 because, again, we believe that the credibility of the
16 EPA is at risk whenever we go back and we review,
17 again, based on some...some new science that's out
18 there that hasn't went through the same review process
19 as the other science has that we've talked about over
20 the last 12 to 14 years.

21 So, we look for the EPA to be non-
22 biased, and...and we hope that the science, in the end,
23 dictates the process. If the science dictates it,
24 we're good to go. If it's politics, we're good to
25 fight.



1 Thank you.

2 **DR. HEERINGA:** Thank you, Mr. Marshall.

3 I believe that Dr. Sass has arrived, and given her
4 earlier priority on the list, I call on her one more
5 time. Jennifer Sass, Jennifer, are you here?

6 **SPEAKER:** She's here, maybe outside.

7 **DR. HEERINGA:** Okay. Maybe she just
8 stepped...let's...I'm going to move on, then, to Mr.
9 Jerry White who is representing the Kansas Corn Growers
10 Association and Kansas Grain and Sorghum Producers
11 Association.

12 Mr. White? I believe we have heard you
13 before, too. Welcome back.

14 **MR. WHITE:** Yes, it's good to be back
15 again.

16 **DR. HEERINGA:** Next up, Jennifer. Mr.
17 White, please, and then we'll go to Dr. Sass. Yes.

18 **MR. WHITE:** Mr. Chairman and members of
19 the committee, I guess it's good to be back again. My
20 name is Jerry White. I'm the executive director for
21 Kansas Corn and Grain Sorghum associations and serve as
22 chairman of the triazine network.

23 The network did submit comments into
24 the...into the docket, and so, I certainly won't go
25 through all of...all of those, but to echo the comments



1 that were made earlier by Mr. Nelson and Mr. Marshall,
2 we certainly are concerned that not only does it appear
3 but I think in some of the not...been documented and
4 reported that the SAP...it's not just the three that
5 we're talking about in 2010 but also, according to a
6 stakeholder conference call that several of us were on,
7 there are additional SAPs, at least one additional SAP
8 beyond September, 2010 that are scheduled in regards to
9 atrazine.

10 And...and, certainly, we understand the
11 process, that as new science comes out, new reports
12 come out, that the Agency has a responsibility and
13 obligation to review the new stuff that comes out and
14 determine if it...or not it warrants a further review
15 by their Science Advisory Panel, and we understand and
16 appreciate that.

17 What we're not sure in this case is how
18 we bypass some of that, what I call more formal
19 internal review by Agency staff and, instead, have gone
20 to a peer review by the New York Times. It seems
21 hardly appropriate. The Agency itself, the assistant
22 administrator, has indicated that...that the media
23 reports are quite a bit of the driver for this.

24 Quite frankly, I'm confused about an SAP
25 topic that's considered a kick-off meeting. It's



1 almost like it's a United Way campaign or, or something
2 like that. It's...it's unusual, and at least from my
3 standpoint, which probably doesn't go back as far
4 as...as many of you, but this is SAP number six for me.
5 So, it's not exactly a new experience.

6 You know, the agricultural community has
7 participated for 15 years on this subject, will
8 continue to participate. We do think the Agency and
9 the SAP has done a...a tremendous job in the past.
10 We've not always liked the positions taken.

11 The positions asserted by the Agency
12 have not always been supported by the SAP, you know, I
13 take you back to a previous administration and the
14 issue of cancer. The...the presentations by the EPA at
15 the time, widely reported again in the media the day
16 before the SAP really began substantive discussions,
17 suggested that, in fact, atrazine should be a
18 carcinogen.

19 At the end of the process, it was not,
20 but let's face it, the media had already had their
21 field day, and they did not go back and readdress it in
22 the same substance that they did report the initial
23 presentations from EPA.

24 So, we've been there. We've seen the
25 process work. We think we'll continue to see the



1 process work, and...and we'll be back, but we...we do
2 point out that there are some very unusual things that
3 seem to be going on.

4 We can appreciate that, but the sanctity
5 of the science that's been a part of this review,
6 it...it's...some of the most concerning things that I
7 guess I've observed is a reference to things like the
8 Bush EPA. And I'm just going to come straight out and
9 say it.

10 In my mind, some of the most substantial
11 science that occurred did not occur during the Bush
12 EPA, if you want to call it that. The cancer issue was
13 number one with a bullet when the special review was
14 initiated, and, quite frankly, the body of science
15 under that was done under the Clinton EPA, if we want
16 to use those targets, and, in fact, the most
17 substantial statement, I think, on public safety
18 probably came out and on the review in total in July of
19 this year by the Obama EPA.

20 So, it's a science that has carried the
21 day through many administrations, and...and we
22 certainly expect that to occur in the future, and I
23 guess we'll look forward to seeing you again.
24 I'm...I'm a little disappointed. I thought maybe I was
25 going to be able to get a chance to hear his comments



1 some more, but I guess I should pass on that.

2 **DR. HEERINGA:** Thank you very much, Mr.
3 White.

4 Just a note for myself as chair that
5 this morning's meeting is a public meeting which is a
6 public meeting of an annual update that the SAP, the
7 permanent members you see here, receive from the EPA.
8 And, generally, it is a...a general coverage of the
9 topics that we expect to come down the pike in the next
10 year and two years.

11 It is a little unusual that it's focused
12 on one topic, but the fact that it's public, I think,
13 in my view, reflects the EPA's interest in making this
14 initial presentation which would, again, just be an
15 administrative discussion with...with the permanent
16 panel about upcoming things, to make that information
17 open and available to the public.

18 At this point, Dr. Sass, we have your
19 public comment.

20 **DR. SASS:** Thank you. I'm glad to be
21 here, and I'm sorry that I was late. I will be here
22 for the rest of the day. So, I will be looking forward
23 to hearing your thoughts as well as the public
24 commenters.

25 My name is Jennifer Sass, and I'm with



1 the Natural Resources Defense Council which is an
2 environmental non-profit, and I'm based here in
3 Washington, D.C., and I'm a senior scientist in the
4 health program. My comments were submitted to the
5 docket about a week ago or whenever they were. As
6 well, I brought 30 copies in with Dr. Bailey to be
7 distributed. So, hopefully, you know, you, at least,
8 can access them at some point if you so desire.

9 So, I'm going to touch on some of the
10 points in the comments. First of all, we're very
11 pleased that the EPA and the scientific advisory panel
12 will be taking a look at the atrazine issue for a
13 number of reasons that are based on some new
14 information that's come in, first of all, some of the
15 monitoring, both water, ecological water monitoring as
16 well as drinking or tap water monitoring information
17 and some new science that's come out in the last few
18 years.

19 As well, this science that was
20 previously available to SAPs in earlier determinations
21 is still very relevant, of course. There's no statute
22 of limitations on the truth, and in this case, I think
23 that the science has been increasing, making a stronger
24 argument supporting the concern that atrazine in our
25 waterways, both drinking water and particularly in the



1 wat...in open and surface water systems is a concern
2 for wildlife.

3 So, first of all, at NRDC, we analyzed
4 the drinking water and the ecological water monitoring
5 data, and we have a report that's available, and I've
6 also provided a summary in my comments.

7 Some of the main points are that the
8 water monitoring from the watersheds, the surface
9 water, showed that all 40 watersheds that were tested
10 had detectable levels of atrazine, and this supports
11 USGS water monitoring also that found widespread
12 atrazine contamination in surface water. 25 of the
13 watersheds that were looked at had average
14 concentrations above 1 ppb which is the concentration
15 at which primary production of aquatic, non-vascular
16 plants such as algae is reduced. So, one would expect
17 or predict that there might be harm to the ecosystem
18 because of that.

19 Nine of the monitored watersheds, which
20 is 22 percent of the total, had at least one sample
21 showing atrazine levels above 50 ppb. This...this
22 isn't an average, but it's a spike or one sample above
23 50 ppb, and four watersheds, representing 10 percent of
24 the total, had peak maximum concentrations that
25 exceeded 100 ppb.



1 So, this is a concern for us for aquatic
2 wildlife as well as aquatic plants that provide oxygen
3 and nutrients to the wildlife in the water.

4 One...at one place, the annual average
5 concentration, that is, an average over the entire
6 year, was 7.5 ppb. This is surface water at Little
7 Pidgeon Creek in Indiana. And the maximum
8 concentration in that location was 237.5 ppb. That was
9 detected in May of '05.

10 We also looked at the drinking water
11 monitoring data, and it also revealed some disturbingly
12 high spikes or short-term peaks. More than 90 percent
13 of the samples taken in the 139 water systems had
14 measurable levels of atrazine over both sampling years.
15 That was '03 and '04. And three water systems had
16 running annual averages for atrazine in the finished or
17 tap water that exceeded the 3 ppb drinking water
18 standard.

19 54 of the water systems, representing 39
20 percent, had a one-time peak atrazine concentration
21 that was above 3, and the highest peak in one of the
22 systems was 36...39.69 in Evansville.

23 So, the...the peaks are a real concern
24 to us because of potential effects on wildlife even
25 during those short-term exposures which might be days



1 or weeks long. They don't actually...they aren't
2 actually considered as peaks, per se, in the regulatory
3 system for drinking water, and that doesn't fall under
4 the Office of Pesticides' jurisdiction in any case.

5 And there's some new science as well
6 that's worth taking a look at. In 2009, there was a
7 number of studies published, and I want to just touch
8 on some highlights from a...a meta analysis that was
9 published by Drs. Rohrer and McCoy. Atrazine in that
10 study...and that was a study on a wildlife species,
11 frogs...found that atrazine reduced size at or near
12 metamorphosis in 19 of the 19 studies that were looked
13 at in the meta analysis. Responses were non-monotonic,
14 meaning that sometimes metamorphosis was delayed, and
15 sometimes it was accelerated.

16 Atrazine reduced anti-predator behavior
17 in six out of seven studies that were looked at, and
18 atrazine is associated with impaired immune function in
19 35 of 42 endpoints. There was an increased rate of
20 infection in 13 of 16 endpoints. And atrazine altered
21 gonadal development in eight out of ten studies that
22 were examined. It impaired gonad function by altering
23 spermatogenesis in two of the two studies that were
24 looked at and altered sex hormone concentrations in six
25 out of seven studies that were examined.



1 So...I'm not going to go through the
2 strengths and weaknesses of meta analyses except to say
3 that it raises some points that I think are worth
4 taking a deeper look at in terms of the potential
5 effects for atrazine on wildlife species, even in
6 spikes or short-term durations.

7 There are some other significant studies
8 that were published in 2009. One study, by Laws,
9 et.al., found that even a single dose of atrazine...it
10 was 200 mg/kg given to male oyster rats...caused a
11 measurable increase in steroid hormone release within
12 15 minutes after dosing, so a rapid response to a
13 short-term spike.

14 In another study, a different study,
15 published in 2009, rats that were fed atrazine
16 contaminated feed for one or two weeks had a dose-
17 dependent reduction in sperm number and impaired daily
18 sperm production. And in another study published in
19 2009, rats that were fed atrazine contaminated feed for
20 25 days had a dose-dependent reduction in steroid
21 production in the leydig cells of the testes.

22 Finally, in another 2009 study, rats
23 that were treated for five months with atrazine-laced
24 drinking water at 330 or 300 ppb, which were within the
25 range of the spikes or peaks that we're seeing in the



1 monitoring program, had associated insulin resistance
2 leading to obesity. I think that one's very
3 interesting, because it's so directly relevant because
4 it was atrazine-laced drinking water was the dosing
5 method, and the dose was just in the ranges of what we
6 see in the monitoring program.

7 So, we are very pleased that EPA and the
8 SAP is willing to take the time to look at this issue
9 again. We have some recommendations for your
10 scientific advisory panel as you put them together.

11 First of all, to gain assurances that
12 EPA will provide all the published peer reviewed
13 studies of relevant data, including but not limited to
14 the animal bioassays, in vitro data, human
15 epidemiology, incident data, and ecological
16 epidemiology, that the questions and...the charge
17 questions and the data provided to you should be broad
18 so that your decision, your determination and your
19 conclusions can be based on...on a broad sweep of the
20 literature.

21 We recommend that SAP get assurances
22 from EPA that it will...its review will not be limited
23 to only studies published since the last review, given
24 that previous SAP reviews did not do comprehensive
25 literature reviews. They were...the charge questions



1 were more limited in those ones.

2 And we recommend that the SAP get
3 assurances that the cancer and non-cancer review will
4 include both human and animal data from published peer
5 reviewed studies, including but not limited to the
6 animal bioassays, in vitro studies, occupational
7 epidemiology, and ecological epidemiology.

8 All data endpoints...all...sorry...all
9 endpoints relevant to cancer, including endocrine
10 endpoints, should be considered in order to help the
11 SAP make a determination that considers the full sweep
12 of the data.

13 Thank you very much for your time to do
14 this.

15 **DR. HEERINGA:** Thank you very much, Dr.
16 Sass.

17 We'd like to move on to our next public
18 commenter. We have three more this morning, and then
19 we'll take a break. It's a little different format.
20 We've gone a little longer than we typically do, but we
21 want to try to get through this period of public
22 comment.

23 At this point, I'd like to ask Rob
24 Schneider who is with the National Corn Growers
25 Association. Mr. Schneider?



1 The remaining discussants in order, just
2 so you can prepare, would be Alex Avery and then Wayne
3 McAllister.

4 **MR. SCHNEIDER:** Good morning. It's good
5 to be with you all today again. My name is Rob
6 Schneider, director of public policy with the National
7 Corn Growers Association, providing comment on behalf
8 of NCGA which represents more than 36,000 members in 48
9 states, 47 affiliated state organizations, and more
10 than 300,000 corn farmers who contribute to state
11 checkoff programs across the country.

12 NCGA's members strongly support the
13 continued use of atrazine as an agronomic necessity on
14 about two-thirds of all U.S. corn. U.S. farmers rely
15 on atrazine for cost-effective broad-leaf weed control.

16 First of all, NCGA is disappointed with
17 EPA's decision to not extend the recent comment period
18 on the atrazine reevaluation approach. According to
19 the Agency, atrazine is one of the most widely used
20 agricultural pesticides in the U.S., with approximately
21 7...70 million pounds of active ingredient applied
22 domestically per year.

23 The chemical has been safely used in the
24 U.S. since 1958, yet the Agency provided only 15 days
25 for interested parties to submit written comments. If



1 EPA was interested in adhering to principles of
2 transparency and sound science, it would have given
3 adequate time for the public to review relevant
4 materials and provide input.

5 In addition, the timing of this proposal
6 in the midst of harvest made it particularly difficult
7 for corn growers to meet the abbreviated deadline for
8 comment submission. EPA's current course of action
9 would suggest that it is prejudging the safety of
10 atrazine, holding this meeting and determining the
11 Agency's course of action within six business days of
12 the close of the condensed comment period.

13 This week's meeting comes on the heels
14 of almost continuous EPA review of atrazine over the
15 past 10 years. The scientific advisory panels convened
16 in 2000 and 2003, 2007, and 2009. There were
17 additional studies already scheduled for 2010 before
18 this current comprehensive review was announced last
19 month.

20 During EPA's recent special review of
21 atrazine, more than 6000 studies were considered in
22 determining that atrazine's registration can be safely
23 maintained. Perhaps what is most alarming is the
24 precedent that is being established by the Agency's
25 current action.



1 Before convening a scientific advisory
2 panel, EPA would typically review any new applicable
3 data or information, weigh its scientific integrity and
4 regulatory significance, and determine the necessity of
5 a new SAP.

6 This...there is no evidence that EPA has
7 thoroughly evaluated any new underlying studies before
8 proceeding with this particular panel. In fact, the
9 Agency is attempting to review a host of issues in the
10 next 12 months that previously took more than a decade
11 to consider.

12 This creates a false sense of urgency
13 and causes our members to question the motivation
14 behind this process.

15 Our growers have always been committed
16 to leaving our environment in better shape than we
17 found it. Stewardship measures ensure that atrazine is
18 used in accordance with the label and applied in a
19 judicious and cost-efficient manner.

20 At the same time, NCGA believes that 50
21 years of safe use and extensive monitoring data support
22 atrazine's continued registration in the U.S. In
23 short, we are simply asking the EPA to stand by its own
24 science.

25 NCGA and myself would like to thank you



1 for the opportunity to comment here this morning.

2 **DR. HEERINGA:** Thank you very much, Mr.
3 Schneider.

4 For our next public comments, I would
5 like to call up Alex Avery of the Hudson Institute
6 where he is director of research.

7 **MR. AVERY:** Thank you for allowing us
8 to...to be here and to comment. I've been in this
9 arena for more than 15 years. I cut my teeth on the
10 infamous Alar scare...scandal, really...that was
11 perpetrated by the perpetrators of this current
12 scandal. And I'm going to call a spade a spade today.

13 The announcement of this review a scant
14 three months after the conclusions that were announced
15 from the last decades-long review does not strongly
16 suggest that this process is being entirely motivated
17 by politics. It gives us a virtual high definition
18 video of the politicization of the regulatory process.

19 It should be noted, as others have, that
20 there was another review scheduled for next fall.
21 There is not a shred of science that's been presented
22 to suggest that a new, urgent, full evaluation is
23 warranted or necessary, but the politics sure...sure do
24 suggest urgency.

25 We all know if the Democrats lose the

1 next presidential election in 2012 that they will also
2 lose the reins on the political machine with which to
3 ban atrazine on political grounds. Hence, a new
4 scientific review of atrazine must start immediately if
5 the Agency and its, more importantly, its political
6 directors are to have a fig leaf of science with which
7 to hide their politically motivated ban or severe
8 restrictions of atrazine.

9 And as the EPA is well aware, a ban or
10 severe restriction on atrazine will mean higher food
11 costs, more soil erosion, less sustainable farming, and
12 more environmental degradation and damage. It will
13 mean putting more of our farming eggs in fewer baskets,
14 and with the inevitable return of bedbugs to our major
15 cities, we've learned the hard way, just recently, how
16 needlessly restricting the tools that we have to fight
17 the scourges of Mother Nature hamstring our efforts.

18 The world's population is continuing to
19 grow, and world food demand is set to at least double
20 over the next 40 years. We need every single tool we
21 have and then some just to keep our heads above the
22 rising tide of agricultural demand.

23 Atrazine is a critical tool in that
24 process. It's also a critical tool in protecting the
25 environment and keeping our agricultural system

1 sustainable. Atrazine and other herbicides are
2 integral.

3 They're at the heart of the no plow, no
4 tillage farming revolution that has caused soil erosion
5 to drop precipitously, thankfully so. Research by the
6 USDA at Beltsville has demonstrated conclusively that
7 no tillage farming suffers less than 20 percent of the
8 soil loss that organic and old-style conventional
9 chillage, tillage plowing methods suffer.

10 And atrazine is a critical tool in that
11 process. It helps us to combat resistance to other
12 weed killers, maintain high...higher soil organic
13 matter contents which is something that EPA is
14 supposedly in favor of when it comes to climate change,
15 and it protects our rivers and streams from
16 sediment...sediment pollution which is also a major
17 concern of the EPA under normal circumstances.

18 The witch hunt against atrazine has been
19 perpetrated for more than a decade by the Natural
20 Resources Defense Council, and they will not take no
21 for an answer. And they realize that they don't need
22 sound science or any good scientific evidence to
23 justify a ban on atrazine. All they know...they know
24 full well that, based on the Alar scandal, that all
25 they need is innuendo. All they need is the suggestion



1 and enough concocted public fear.

2 And, hence, suggestions today from
3 the...the one who came before me that atrazine is now
4 responsible for the obesity epidemic in the United
5 States.

6 So, back in the 21st century, the
7 Natural Resources Defense Council was trying to do to
8 atrazine what they did to Alar. Make no mistake, the
9 NRDC and the political operators running the EPA today
10 will go back to the scientific wishing well until they
11 create enough innuendo and fear to cover a politically
12 motivated, ideological effort to ban or severely
13 restrict atrazine.

14 We are watching. We will fight it. We
15 are not going away.

16 Thank you.

17 **DR. HEERINGA:** Thank you, Mr. Avery.

18 And now, not Wayne McAllister but Ray McAllister from
19 Croplife America.

20 **MR. MCALLISTER:** Thank you. I apologize
21 for not having copies of my comments, but I'll make
22 those available through the Agency.

23 Croplife America is a trade association
24 which represents the common interests of manufacturers,
25 formulators, and distributors of virtually all the



1 active ingredients used in crop protection products in
2 the United States. We're commenting today because of
3 our concern about the Agency initiating a...a review of
4 a compound that has been reviewed almost continuously
5 for more than 20 years, and the Agency has put a great
6 deal of effort into this already.

7 In the course of making regulatory
8 evaluations and decisions on individual products, the
9 potential exists to set new policies and alter existing
10 ones which will affect subsequent decisions across the
11 board. That's our concern about the initiation of this
12 review today which does not appear to be entirely
13 motivated by science-based principles. We are not
14 aware of any basis in...in real fact or law to reopen
15 the long series of Agency decisions which are based on
16 years of data on record and many years of the Agency
17 analysis.

18 We're concerned that this...this
19 decision for a new year-long review has been taken
20 rather hastily and is based on un...unsubstantiated
21 media...media reporting and reports of an activist
22 organization over alleged human health effects and
23 concerns and criticisms of EPA's regulatory oversight.
24 The Agency announces as much in its public docket.

25 The Agency is well aware of the



1 importance of basing its rulings on sound science and a
2 transparent progress, allowing adequate time for public
3 participation. That is their statutory obligation, to
4 adhere to these principles and frequently re..restate
5 them in their communications regarding such actions
6 and...and activities of the Agency.

7 Yet, this year-long review of atrazine
8 involves a compound which has been in use for 50 years.
9 It's been under a number of different types of reviews,
10 many of them or some of them only recently concluded.

11 The Administrative Procedures Act
12 requires notice and comment on actions by Federal
13 agencies for a number of reasons. Public participation
14 and fairness to affected parties is a principal reason.
15 It ensures that the agency will have before it the
16 facts and information relevant to a particular
17 administrative problem, and it allows an agency to
18 reconsider and sometimes change its proposals based on
19 the comments of affected persons.

20 It doesn't specify a minimum comment
21 period, but even providing 30 days to comment for
22 the...from the publication of a Notice in the Federal
23 Register might not be an adequate period of time to
24 respond to proposals that are complex or based on
25 significant scientific and technical data.



1 In this case, the compressed time
2 schedule between publication of the notice of the
3 meeting on October 7th and the call for public
4 comments, a little more than two weeks later, for a
5 meeting even just two weeks after that precluded
6 considered and thoughtful comments on the review of the
7 proposal by the public.

8 This compressed schedule also
9 affected...gives the impression that EPA has prejudged
10 the critical aspects of the year-long review of this
11 compound and leaves no time for reasoned comment
12 development by commenters, much less review of such
13 comments by the EPA and adequate time for you, the SAP,
14 to...to review and make appropriate recommendations to
15 the Agency.

16 Under these circumstances, are we, as
17 regulated entities and the regulated community, to
18 conclude that EPA is establishing a new paradigm to
19 take groundless and unsub...unsubstantiated information
20 from the press and from activist organizations to start
21 a new review of a compound? NRDC cites studies that
22 have been reviewed numerous times and discounted by the
23 experienced EPA scientists due to defects, flaws, or
24 lack of quality in those studies.

25 We're concerned that this is a...this is



1 a divergence from the science-based process under FIFRA
2 FQPA. EPA has done special reviews of triazines that
3 took place over 12 years, concluded just 3 years ago.
4 It has planned a registration review of atrazine to
5 begin in just a few years from now. So, dropping
6 another comprehensive year-long review in the midst of
7 these other reviews in progress or recently concluded
8 or on the schedule appears to be politically motivated,
9 and we're concerned that this sets a precedent for
10 other...other products in the marketplace where a
11 review may be unjustified.

12 Thank you.

13 **DR. HEERINGA:** Thank you, Mr.
14 McAllister.

15 A note to the presenters here during the
16 public comment period. If you have a written version
17 of your comments, including the version that you used
18 to read from, and have not provided it for the docket,
19 I would encourage you to do that, to provide it to
20 ...to Joe Bailey who is the Designated Federal Official
21 for this meeting.

22 At this point in time, I'd like to draw
23 the period of public comment to a close and call for a
24 15-minute break at which time our meeting will
25 reconvene, and we will have an opportunity, as we would



1 typically in our permanent panel administrative
2 meeting, to address some questions to the scientific
3 and administrative staff of the EPA.

4 So, let's all rejoin here about...oh,
5 let's say 11:25, and we'll continue until about the
6 noon hour.

7 **(WHEREUPON, a brief recess was taken.)**

8 **DR. HEERINGA:** Okay, welcome back,
9 everybody, to the second half of our...our morning
10 session, our morning meeting in which the panel is
11 hearing from the EPA and from public commenters on the
12 topic of the presentation of the approach to reevaluate
13 atrazine.

14 At this point in time, we have on the
15 agenda a period of time for the...the panel to discuss
16 the material that we've heard this morning and to maybe
17 ask questions of Dr. Bradbury and Dr. Levine, Dr.
18 Lowit, and others on the staff who will be working on
19 this particular effort.

20 I would like, if we could, to bring out
21 the slide number 1 from Dr. Bradbury's presentation
22 which is the...the columns are the three monthly
23 meetings, and the rows are sort of a summary of content
24 in each of those three meetings if we could.

25 And while that's...while that's coming



1 up, I guess I'd like to open up to my fellow panel
2 members the floor to ask questions based on, again, the
3 presentations this morning on the nature of this
4 initiative. Does anyone want to take a leap? Dr.
5 Portier?

6 **DR. PORTIER:** So, thinking about
7 these...these upcoming meetings and, in particular,
8 looking at the February meeting, we had a...we had a
9 meeting last year where we looked at the three
10 epidemiology studies from California. I don't know if
11 you remember that meeting. Was it last year or
12 year...late year before last? It was last year, early
13 last year.

14 The community health work...the
15 bystander exposure in epidemiology, but I just remember
16 that panel and remember having a lot of discussion. I
17 think it's going to be of importance for the panel to
18 kind of see the questions for that meeting a little bit
19 early so we can really understand what you're trying to
20 get at in those questions.

21 It's been my experience on the panel
22 that every time epidemiology studies come up, there's a
23 lot of discussion and a lot of confusion. We spend a
24 lot of time trying to understand the value of those
25 studies, and sometimes, they're underpowered or



1 undersized, and then we're trying to figure out what
2 are we really getting out of these...out of the
3 studies.

4 And then, I guess, the second thing is
5 if...if what we're going to be looking at is the
6 agricultural workers study design, if you're going to
7 be asking the panel to look at that design, to
8 anticipate what we might be getting from that, it would
9 be nice to be able to see those design parameters.

10 We...we were talking at the break about
11 things like at this point, they should know roughly
12 what their...their data collection rates look like,
13 missing data, what kind of things it characterized,
14 what kind of...what...what they actually measured, so
15 we can be looking at those parameters and
16 anticipating...I don't know if February's linked to
17 September. In September, I'm thinking we're looking at
18 the results of those studies. Right? Of whatever's
19 published out of that study over the spring and the
20 summer.

21 But if we're looking at kind of the
22 value of epidemiology, we're going to need to
23 understand up front what that...what was...what went
24 into that particular study.

25 **DR. HEERINGA:** Dr. Chambers?



1 **DR. CHAMBERS:** With respect to the
2 February study, it sounds like incorporating epi
3 studies and human health incident data into risk
4 assessment is a very important generic topic, and I
5 assume that was what was on the table for February,
6 anyway. I guess my question would be, is the atrazine
7 data set really relevant to those particular questions,
8 or are we going to get bogged down on just the
9 individual atrazine data set? Because the generic
10 questions, I think, might be broader than just the
11 individual studies and...

12 **DR. LEVINE:** Well, actually, in my
13 remarks, I think I tried to stress that we don't want
14 that session to get bogged down to...into just being
15 about atrazine, but...but we always envisioned
16 this...this, the February session to have some case
17 study examples.

18 And...and, in actuality, we had thought
19 that they would be more of the data out of the Ag
20 Health study that we could use, but that wasn't
21 happening which is part of the reason it seems to get
22 postponed and postponed, and since there were a number
23 of different designs, designs that are different from
24 the Ag Health study that were...were...have been cited
25 in the media about atrazine risk and there are



1 other...probably other studies, too, we thought they
2 would make good case studies. And, in addition, we
3 have some incident case studies, and we'd always
4 planned to do it that way.

5 So, it's really going to be one of the
6 illustrations, but it's going to be about the more
7 generic issue.

8 **DR. LOWIT:** And, Dr. Chambers, the only
9 thing I would add to that...Anna Lowit. The only thing
10 I would add to that is...is that the atrazine studies
11 that we'll talk about are not, although they're unique
12 to atrazine, those questions are not unique to
13 atrazine, and there's not a unique situation where
14 studies are published in the open literature that, on a
15 pesticide chemical.

16 There's...questions always arise of how
17 to incorporate that into our risk characterization.
18 So, we share a concern of having atrazine not overwhelm
19 that meeting and to focus on the broader intent, but I
20 think the answer to your question is simply yes, the
21 questions that we'll ask about those studies fit very
22 well in that meeting, I think.

23 **DR. HEERINGA:** Dr. Bucher?

24 **DR. BUCHER:** John Bucher. I think the
25 same kinds of comments could be made about the



1 references that you made, Dr. Bradbury, to the
2 toxicology in the 21st century with respect to the
3 ToxCast program that...the generation of data from in
4 vitro assays and how that's used in risk assessment,
5 and I'm...I'm not...I don't know exactly...in my own
6 mind, I'm not sure exactly how mature that, the
7 appreciation of all that information is going to be
8 with respect to also inserting the atrazine issues in
9 that regard.

10 So, I...I guess I just had some of the
11 same concerns with that, that were just expressed.

12 **DR. BRADBURY:** With regard to...if I
13 could read a little bit more into your question with
14 regard, especially, to the April SAP, what we want to
15 ensure that, consistent with Agency guidance on using
16 best available information and developing of lines of
17 evidence and weight of evidence to try to characterize
18 the risk as best we can, think about the uncertainty
19 either qualitatively or quantitatively.

20 We want to ensure that we're taking
21 advantage of any in vitro information in the course of
22 the data quality review of that data to see to what
23 extent it can help inform us as to the mechanisms of
24 action, mode of action of atrazine and how is that
25 information concurrent with other experimental



1 toxicology information we review in April to see can we
2 put together a coherent picture, maybe update the
3 picture or maybe it's a new picture, in terms of what
4 do we know about the mechanisms of action, toxicity
5 pathways associated with atrazine and/or its
6 metabolites and how does that lead to adverse outcomes,
7 which we feel is an important part of doing a risk
8 assessment today.

9 And we'll continue to advance that...the
10 ability to try to integrate that information, to use
11 toxicity pathways, mode of action to help inform dose
12 response relationships, to help inform what may be
13 similar or dissimilar across species and understand
14 aspects of...of exposure considerations in terms of
15 characterizing the risk.

16 So, that...April will be atrazine, but I
17 think it's fair to say we'll not only advance
18 our...and...and update our understanding of atrazine,
19 but we'll probably get some other insights that can be
20 more broadly applicable to integrating diverse sets of
21 information together, especially as these go from April
22 to...to September where experimental studies are being
23 integrated with epidemiology studies.

24 If I could just comment a little bit on
25 the earlier question about February/September, the

1 epidemiology studies, to...to reinforce what Dr. Levine
2 was saying, our goal all along in February was to have
3 a risk assessment to look at approaches for including
4 incident data, as appropriate, as well as epidemiology
5 studies, as appropriate, based on data quality and
6 designs, all those issues, into a robust risk
7 characterization and integrating this information.

8 February, in a sense, is a building
9 block step as we move forward. And so, atrazine
10 provides us some opportunity to explore some
11 epidemiology designs as well as get some insights on
12 some specific studies. I'm not an epidemiologist. I
13 mean, I don't wear that hat, but my colleagues are
14 explaining to me that there's a spectrum of design
15 types from ecologic studies to retrospective case
16 studies to prospective studies, and what we want to
17 look at in February, in particular, are ecologic
18 designs and retrospective designs and get some sense as
19 to how you interpret that kind of information along
20 with other kinds of information.

21 As we move to September, we'll be
22 looking at the Ag Health study which is a prospective
23 study which is a different design. We'll ultimately
24 get some advice from you on how do we integrate these
25 different kinds of epidemiology studies, designs or



1 strengths and limitations in the context of the animal
2 or experimental toxicology data that we'll also have
3 available.

4 **DR. HEERINGA:** Steve Heeringa. I'd like
5 to introduce just a few comments of my own and...and
6 these are my own views here and don't necessarily
7 reflect those of the complete panel.

8 In the over...over a decade that I've
9 been involved in the process with the ad hoc panels as
10 a person who sat and provided advice or serving on the
11 permanent panel, this is a little out of the ordinary,
12 but I...certainly, it's not my position right now to
13 question your judgment or the motivation on this.

14 We are an advisory panel and here to
15 serve you objectively to help interpret science, and I
16 think I certainly have worked with you long enough and
17 have enough confidence to know that when you come to
18 us, it's for a purpose to seek out scientific review on
19 new information.

20 That said, this is going to be a very
21 busy year, and these are going to be very demanding
22 reviews not only for the permanent panel but also for
23 the ad hoc members. And you know that the ad hoc
24 members play a key role in these reviews. And it's
25 going to be essential in this process, as it goes



1 forward...it's...it has some pretty broad aims, and I
2 think, scientifically, as I say, we're prepared to help
3 you evaluate those aims, and that's what we're going to
4 do.

5 But it does mean that data sources,
6 materials, background materials should be ready early
7 in this process for review. The amount of data
8 alone...if I think about even the April meeting with
9 the sort of reassessment and look at the experimental
10 toxicology studies could easily overwhelm reviewers,
11 and I want to make sure that, as we go through this
12 process as a panel, to be fair to you and to be fair to
13 us, that we, in fact, have time to prepare.

14 And looking ahead to September with the
15 Agricultural Health study...I have some knowledge of
16 this because of participations in the meeting, but I
17 don't know anything about the design.

18 Maybe it's a simple trip to the...to the
19 web to learn some of that information, but I would
20 say...ask of you in terms of your working with the
21 permanent panel and also with the ad hoc panels that
22 are formed that as soon as you have data and
23 documentation that you can provide to us, it would be
24 important for us to receive this even in advance of
25 receiving the charge questions.



1 Because while the charge questions will
2 help focus our scientific response to your concerns and
3 your issues, I think it's very important in this very
4 data intensive set of reviews for us to be able to
5 become directly familiar with most of these information
6 sources.

7 And...and we can communicate on that,
8 too, but I just want to emphasize that, again, what
9 you've presented here in terms of a scientific review,
10 and we anticipate your request of us as an advisory
11 panel on that science as we move ahead, please help us
12 be prepared to do this. And we'll keep a close eye,
13 too, because we want to make sure that there is
14 adequate time for these reviews and for consideration
15 of all of the information.

16 Additional comments? Dr. Chambers?

17 **DR. CHAMBERS:** As just a followup to
18 Steve's remarks, then, if...if the data really can't be
19 compiled in a well organized and well analyzed manner
20 in time for those particular meetings, you've put
21 meetings off before when they haven't been prepared,
22 and maybe you should put those off, because we really
23 do absolutely, the same thing Steve said, we absolutely
24 need enough time to look at the materials.

25 **DR. HEERINGA:** Any other comments or



1 information? Steve?

2 **DR. BRADBURY:** Seeing if any of my
3 colleagues had any followup questions. I want to take
4 the opportunity to maybe clarify a few things and a
5 little bit of feedback and, you know, move on.

6 First of all, I want to thank you all
7 for spending the time with us this morning on an
8 informational session just to share with you where we
9 are, where our vision is in terms of taking a look at
10 the science around atrazine.

11 As we mentioned before many times,
12 administrative sessions are not public sessions, but we
13 felt it was very important for this particular topic,
14 as we look forward to the 2010 season, that we have a
15 transparent session, we have an open meeting so people
16 could provide some of their initial thoughts and
17 clearly as we move forward through these three peer
18 reviews.

19 And I certainly appreciate the timing
20 and the need to get information in the docket as we
21 form the charge questions.

22 But I just want to reaffirm that the
23 process we use for each of these three SAPs will be
24 like the process we typically use where information is
25 put in the docket, there's opportunity for the public



1 to provide nominations to our colleagues and the
2 designated official, federal officials, to vet a robust
3 panel as well as the opportunity for people to look at
4 the materials going into the docket and provide their
5 insights on the information as well as their views
6 on...on the charge questions as they're formulated as
7 well as to offer you other issues that they think, the
8 public thinks, are important to...to focus on.

9 And so, I just want to reassure the
10 public as well as the panel that we will be using that
11 same process that we've always done in terms of
12 transparency and openness to get information. And,
13 clearly, we will have a number of people working very
14 hard to provide information as soon as we can, and
15 we'll be working with Laura Bailey and others to ensure
16 we have a good process in doing that, in getting
17 information to you ahead of time.

18 And clearly, we value the input that
19 you're going to be providing over the coming 12 months
20 or so as we take a look at these issues.

21 The last comment I wanted to make was
22 just to make it really clear again that when we come to
23 the Science Advisory Panel it's to get advice on
24 important scientific issues, and, clearly, scientific
25 issues are the foundation for any and all of our



1 regulatory decisions, and we don't make regulatory
2 decisions without having a good understanding of the
3 science.

4 And so, coming to you is an important
5 step in evaluating this compound and ensuring that we
6 have the most current and accurate insights as to how
7 to interpret the risk characterization of atrazine.
8 And it's clearly our process consistent with
9 Administrator Jackson's process of very strong science,
10 the rule of law and transparency in how we make
11 decisions, and the Science Advisory Panel looking, the
12 scientists in OBT and ORD and Office of Water is an
13 important foundation to...to how we take a look at this
14 chemical and...and just to reassure everyone that the
15 first step is making sure we're current with the
16 science, we understand the science well and have
17 the...the advice and input from this panel to help
18 guide us in thinking about the science and that's the
19 step that we're at right now.

20 So, I just want to close by thanking you
21 all for spending time with us this morning and...and
22 into the future, and we're very conscious of the
23 aggressive schedule and the need to provide information
24 in a timely manner.

25 Thank you.



1 **DR. HEERINGA:** Well, the lights dimmed
2 because there was no activity. There was thought
3 process going on, but I...apparently, it dropped to a
4 certain level and it cut the juice.

5 So, Dr. Bradbury, if I could, just one
6 more question. With regard to the epidemiology
7 studies, the non-cancer that we'll consider in February
8 and the cancer that we'll consider in...in September,
9 are you aware of current work? Have you seen draft
10 manuscripts on studies on ag health that motivate those
11 agenda items? Or is it just the anticipation of the
12 data release itself, the final data cleaning at a
13 certain stage opens this up for reanalysis and
14 publication?

15 **DR. BRADBURY:** With regard to the...the
16 cancer effects in epidemiology, I mentioned in my
17 opening remarks some of the regulatory process that
18 atrazine is, is in. And atrazine is still in special
19 reviews. The special review for atrazine hasn't been
20 closed.

21 And the special review for atrazine and
22 its primary focus was the extent to which atrazine
23 could be a carcinogen and the potential carcinogenicity
24 of atrazine. So, throughout our...our regulatory game
25 plan time line for atrazine which includes closing the



1 special review, before we can close the special review,
2 we needed to take a final look at atrazine and its
3 potential for carcinogenicity.

4 And consistent with the 2003 IRED, it
5 indicated that the Ag Health study that was ongoing,
6 getting started at the time, and the forecasting for
7 when the last atrazine studies would be completed would
8 be roughly in this time frame.

9 So, that 2010 SAP was always scheduled
10 to deal with the Ag Health study and the cancer studies
11 within the Ag Health study as that last critical step
12 of the science to then determine if we can close the
13 special review for atrazine which had this remaining
14 step in it.

15 Our colleagues in ORD and R&D and our
16 individuals here in OBT with Carol, are working closely
17 with colleagues in the National Cancer Institute and
18 NIEHS, and it's our understanding that those final, I
19 think it's two or three studies should be getting
20 completed in the spring time frame, hence that's why we
21 had scheduled September.

22 With regard to the other epidemiology
23 studies, right now, we're focusing on studies that have
24 been published in the peer reviewed journals. To the
25 extent the Ag Health studies are looking at non-cancer



1 issues and they're coming to bear at the time, we
2 would...we would fold those in as well.

3 So, our primary focus for Ag Health
4 study was largely cancer, the last science step to
5 determine if we can close the special review for
6 atrazine. The other studies is more consistent with
7 our holistic look at...at atrazine, epidemiology
8 studies have been published since 2003 on non-cancer.
9 We want to take a look at those. See how the different
10 designs should be considered.

11 Again, we will be focusing on
12 information that's been published in the peer review
13 literature. To the extent something hasn't been
14 published in the peer review literature, by definition,
15 it's very difficult for us to review that. To the
16 extent, I suppose if an individual or a research group
17 wanted to submit their studies to the docket before
18 they submit it into a journal, we would certainly take
19 a look at them.

20 **DR. HEERINGA:** Thank you very much. Any
21 other questions?

22 (No response.)

23 **DR. HEERINGA:** Well, at this point, I
24 guess I'd like to turn the morning's proceedings over
25 to Joe Bailey to see if there's any final



1 administrative notes, and then we'll wrap up.

2 I'd just remind everybody that the FIFRA
3 SAP will reconvene...it's a larger group this
4 afternoon...to address the topic of nanosilver, and
5 that meeting will be chaired by Gary Pope, my colleague
6 this afternoon, so we hope to see many of you back here
7 for that this afternoon.

8 Joe?

9 **MR. BAILEY:** Thank you, Dr. Heeringa.

10 One note. Security has come forward and
11 said there is a Toyota Forerunner on lower level 2 with
12 the interior lights on, so if it's yours...it has
13 Maryland plates. If it's yours, you might want to
14 check it, or you will have to stay here for the rest of
15 the meeting. If you weren't planning to.

16 And in closing, I just want to thank
17 everyone for attending and express my appreciation to
18 EPA staff and to the public commenters for their
19 presentations. And I want to thank the panel and Dr.
20 Heeringa for being here.

21 Thanks.

22 **DR. HEERINGA:** Yes, thank you, everyone,
23 and we appreciate all of the participation, to the EPA
24 scientific staff for their initial presentations and
25 for bringing us to an open and public, transparent



1 discussion and for all of the public commenters for
2 their input, and we look forward to seeing everyone
3 over the course of the next year on this topic.

4 (WHEREUPON, the Meeting was adjourned at 11:55 a.m.)

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